NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain

Problems with the sacroiliac joints can cause lower back pain. These joints are at the bottom of the back where part of the spine called the sacrum joins part of the pelvis called ilium. Minimally invasive sacroiliac joint fusion surgery is done through a small cut in the skin. It aims to stabilise the joint by fixing the sacrum to the ilium. It involves drilling small channels through the 2 bones and then fixing them together using 2 or 3 metal implants.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in October 2016.

Procedure name

- Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain

Specialist societies

- British Association of Spinal Surgeons.

Description

Indications and current treatment

Chronic pain in the lower back triggered from the SI joint occurs in 15% to 30% of patients with low back pain. The causes of SI joint pain include degenerative sacroiliitis, osteoarthritis, SI joint disruptions from trauma or pregnancy, problems after lumbar spinal fixation techniques, anatomical abnormalities such as scoliosis, infection, gout, tumour or idiopathic causes.

Conservative treatments for SI joint pain include analgesics, non-steroidal anti-inflammatory drugs, physiotherapy, manipulative therapy, intra-articular SI joint corticosteroid injections, periarticular injections, botulinum toxin injections and radiofrequency denervation. Surgical treatment is considered for persistent chronic symptoms that are unresponsive to conservative treatment. Surgical techniques include open SI joint fusion surgery or minimally invasive SI joint fusion using percutaneous implants to stabilise the joint and treat joint pain.

What the procedure involves

Minimally invasive surgical fusion of the SI joint is done with the patient under general or spinal anaesthesia and in a prone position. Fluoroscopic guidance is used. Using a lateral transarticular approach, the SI joint is accessed laterally through a small incision made in the buttock to reach the ilium. A pin is passed through the ilium across the SI joint into the centre of the sacrum, avoiding the neural foramen. A drill is then used to create a pathway through the ilium to the sacrum. An implant is inserted (with the lateral portion of the implant sitting in the ilium and the medial end in the sacrum), spanning the SI joint. Typically 3 implants are used.

Treatment of both SI joints can be done at the same time, or in staged procedures. After surgery, patients are advised to make a gradual return to full weight bearing over several weeks, using a walker for assistance, and subsequent physiotherapy.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain. The following databases were searched, covering the period from their start to 01-08-2016: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search

strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with chronic sacroiliac pain.
Intervention/test	Minimally invasive sacroiliac joint fusion surgery.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 7049 patients from 2 randomised controlled trials[1-2], 2 systematic reviews[3-4], 3 prospective cohort studies[5,6,8] and 2 retrospective case series[7,9].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain

Study 1 Polly DW (2016)

Details

Study type	Randomised controlled trial
Country	US (multicentre)
Recruitment period	2013-14
Study population and number	n=**148** patients with sacroiliac joint (SIJ) dysfunction **(102 minimally invasive (MI) SIJ fusion [MI SIJF] group versus 46 non-surgical management [NSM] group).** Condition: MI SIJF: degenerative sacroilitis 86% (88/102); SIJ disruption: 14% (14/102) NSM: degenerative sacroilitis 87% (40/46); SIJ disruption: 13% (6/46) Prior lumbar fusion: MI SIJF: 39% (40/102); NSM: 37% (17/46) Mean duration of pain: MI SIJF: 7.0 years; NSM: 5.0 years Prior treatments: MI SIJF: physical therapy [n=71], steroid SIJ injection [n=85], radiofrequency ablation (RFA) [n=20], opioids [n=69]. NSM: physical therapy [n=36], steroid SIJ injection [n=42], RFA [n=4], opioids [n=29].
Age and sex	MI SIJF: mean age 50.2 years; 74% (75/102) women; NSM: mean age 53.8 years; 61% (28/46) women
Patient selection criteria	Adult (21-70 years) patients with a diagnosis (medical history, physical examination) of SIJ dysfunction caused by degenerative sacroilitis or SIJ disruption, with baseline score of 30% on the Oswestry disability index (ODI) and SIJ pain score of 50 on a 0-100 visual analogue scale (VAS) were included. Patients with inability to confirm pain arising from the SIJ, SIJ pain secondary to inflammatory conditions, severe back pain due to other causes (lumbar disk degeneration, etc.), recent major trauma to the pelvis, metabolic bone disease, any condition that made treatment infeasible or interfered with the ability to participate in physical therapy were excluded.
Technique	**MI SIJF surgery** with triangular implants (iFuse Implant system) (typically 3) using a lateral approach under fluoroscopic guidance. 1-3 weeks after surgery, patients had physical therapy twice a week for 6 weeks. **NSM:** regimen included anti-inflammatory and pain medications, physical therapy according to American Physical Therapy Association (in1), SIJ steroid injections (in 34), RFA (in 21), delivered in a stepped care approach and tailored to each individual patient's needs. 40 patients had at least 2 types of treatments in addition to medications. **Crossover:** 79.5% (35/44) NSM patients crossed over to MI SIJF after 6-months and 20% (9/46) did not.
Follow-up	**MI SIJ fusion: 24 months; NSM: 6 months post-fusion**
Conflict of interest/source of funding	Study was sponsored by the device manufacturer.

Analysis

Follow-up issues: follow-up rates were high, 13 patients in MI SIJF group and 10 patients in NSM group were lost to follow-up by 24 months.

Study design issues: prospective, multicentre, unblinded trial in 19 centres. Crossover design, randomisation was computer generated and stratified by site and underlying diagnosis in a 2:1 ratio with randomly chosen block sizes of 6 or 9. Primary outcome was success rate, secondary outcomes included improvement from baseline in SIJ and back pain (measured using a 100 point VAS scale), back dysfunction (using ODI) and quality of life scores (as measured by EuroQol-5D and SF-36 PCS) at scheduled visits to 24 months. Cross over from NSM was allowed after 6 months visit. No NSM subjects crossed over early. Both surgical and non-surgical groups received physical therapy. The proportion of patients with clinical improvement (SIJ pain improvement >20 points, ODI >15 points) and substantial clinical benefit (SIJ pain improvement >25 or <35 points, ODI>18.8 points) were compared.

Study population issues: baseline patient characteristics were similar between the 2 groups. Pain location was largely centred over the posterior superior iliac spine but distant pain was also reported. Hip and spinal disease was common in these patients.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **148 (102 versus 46)**

Success rate~ at 6 months

MI SIJF group % (n=102)	NSM group % (n=46)	Bayesian posterior probability of superiority
81.4 (83/102) 95% PCI 72.4-88.4	26.1 (12/46) 95% PCI 14.3-41.1)	>0.9999

~defined as composite endpoint of reduction from baseline in VAS back pain score by at least 20 mm, lack of device-related serious adverse events, absence of neurologic worsening and absence of surgical re-intervention.

Subgroup analysis showed similar differences between success rates associated with SIJ fusion and NSM according to underlying diagnosis, a history of prior lumbar fusion, smoking status or unilateral versus bilateral SIJ pain.

Safety

Adverse event^ rate

	MI SIJF (n=102)	NSM (n=46)	p value
6 months	1.3 (129 events)	1.1 (49 events)	0.31
12 months	1.8 (179 events)	1.9 (89 events)*	0.45

*includes crossover patients.

^ according to international clinical trial standard reported all negative changes in health.

Improvement in pain and disability scores

	MI SIJF (n=102)				NSM (n=46)			
	Baseline	**6 months**	**12 months**	**24 months**	**Baseline**	**6 months**	**12 months**	**24 months**
SIJ pain score (VAS)^ mean	82.3	30.4 p<0.001	28.3 p<0.001	26.7 p<0.001	82.2	70.3 p=0.001		
SIJ pain score (VAS)^ by 20 points, % (n)	84 (84/100)	83.2 (84/101)	81.0 (81/100)	83.1(74/89)	29 (13/45)	27.9 (12/43)	10 (4/40)	10(4/40)
SIJ pain score (VAS)>25/<35points, %(n)	79 (79/100)	79.2 (80/101)	79.0 (79/100)	82 (73/89)	24.4 (11/45)	18.6 (8/43)	7.5 (3/40)	10 (4/40)
ODI^^ score, mean	57.2	29.9 p<0.001	28.1 p<0.001	28.7 p<0.001	56.0	51.6 p=0.06		
ODI^^ score by 15 points, % (n)	49 (49/100)	73 (74/101)	72.4 (72/100)	68.2 (60/88)	13.3 (6/45)	13.6 (6/44)	7.5 (3/40)	7.5 (3/40)
ODI score^^ >18.8 points, % (n)	44 (44/100)	62.4 (63/101)	66 (66/100)	65.9(58/88)	6.7 (3/45)	11.4 (5/44)	5 (2/40)	7.5 (3/40)

^VAS 0-100mm, where 0 represents no pain and 100 represent the worst imaginable pain. ^^ODI is a validated 10 question survey for disability from back pain.

Adverse events over 12 months

	MI SIJF % (n=102)	**NSM % (n=46)**
Arm/hand	9 (9/102)	6.5(3/46)
Back pain	17 (17/102)	17 (8/46)
Cardiovascular	8 (8/102)	2 (1/46)
Endocrinological	3 (3/102)	2 (1/46)
Fall	2 (2/102)	2 (1/46)
Foot	1 (1/102)	0
Gastroenterological	14 (14/102)	11 (5/46)
Genitourinary	5 (5/102)	2(1/46)
Gynaecologic	1 (1/102)	0
Hematologic	1 (1/102)	0
Infection	5 (5/102)	7 (3/46)
Leg pain	32 (32/102)	50 (23/46)
Other	4 (4/102)	9 (4/46)
Neck pain	4 (4/102)	2 (1/46)
Pelvis pain	48 (48/102)	46(21/46)
Psychiatric	1 (1/102)	2 (1/46)
Pulmonary events	2 (2/102)	11 (5/46)
Shoulder	1 (1/102)	2 (1/46)
Surgical wound	5 (5/102)	4 (2/46)
Trauma	16 (16/102)	17 (8/46)
All	**179**	**89**

78 of these adverse events were severe (55 in SIJ fusion and 23 in NSM). 2 deaths occurred in SIJ fusion group, 1 due to pulmonary fibrosis and chronic obstructive pulmonary disease and 1 from a fatal myocardial infarction.

There were no statistically significant differences in rate of adverse events across 2 two groups.

Improvement in quality of life outcomes

	MI SIJF (n=102)				NSM (n=46)		
	Baseline	**6 months**	**12 months**	**24 months**	**Baseline**	**6 months**	**P value across groups**
EQ-5D-TTO*	0.44 ±0.18	0.72±0.22 p<0.001	0.74±0.20 p<0.001	0.72 p<0.001	0.47± 0.19	0.52±0.23 p=0.17	<0.001
SF-36 PCS**	30.2 ±6.2	42.6±10.1 p<0.001	43.1±10.3 p<0.001	41.4 p<0.001	30.8± 6.1	32.1±7.6 p=0.30	<0.0001
SF-36 MCS**	43.0 ±11.5	49.2±11.4 p<0.001	50.4±11.0 p<0.001		43.3± 12.1	44.0±12.5 p=0.70	0.006

*EQ-5D is a 5 question broad quality of life measure combined into a single index and represents TTO utility of current health; higher scores indicating better health.

** SF-36 is a 36 question, 8 subscale generic quality of life measure that summarises overall physical and mental health (PCS and MCS) with equivalent population norms. Higher scores indicate better health.

Outcomes in cross-over patients

	Crossed (n=35/44)			Did not cross/withdrew (11/44)			P value across groups
	Baseline	**6 months**	**12 months**	**Baseline**	**6 months**	**12 months**	
SIJ pain score (VAS) mean	83.9	79.0 p=0.04	35.8 p<0.001	76.5	37.3 p=0.005	54.3 p=0.045	<0.001 at 12 months
ODI score mean	58.3	56.1 p=0.40	30.2 p<0.001	48.9	34.1 p=0.01	34.0 p=0.98	<0.001 at 12 months
EQ-5D-TTO	0.45± 0.18	0.47±0.20 p=0.66	0.73±0.22 p<0.001	0.53± 0.22	0.73±0.20 p=0.009	0.74±0.12 p=0.008	0.09
SF-36 PCS	30.4± 6.4	30.5±6.5 p=0.90	42.4±10.6 p<0.001	32.1± 4.9	38.2±9.8 p=0.11	37.8±9.5 p=0.09	0.07
SF-36 MCS	43.3± 12.0	43.0±12.1 p=0.84	50.7±9.4 p=0.002	43.2± 13.2	47.9±14.1 p=0.26	46.2±9.8 p=0.36	0.24

Satisfaction rate

	MI SIJF % (n=102)	NSM % (n=46)	P value across groups
6 months	77.2	27.3	<0.001
12 months	77.6		
24 months	73.3		

Satisfaction rate 6 months after surgery in cross over NSM patients was 71% (22/31).

The proportions of patients who would definitely have the SIJ fusion again were 79.2%, 75%, and 71% at 6, 12 and 24 months respectively.

Adverse events related to device or procedure within 6 months

	MI SIJF % (n=102)	NSM % (n=46)
Device related	3 (3/102)*	-
Procedure or NSM related	19 (19/102) neuropathic symptoms in 1, postoperative medical problems in 4(urinary retention-1, nausea/vomiting-2, atrial fibrillation-1) SIJ pain or trochanteric bursitis in 7, surgical wound problems in 5, iliac fracture in1, asymptomatic physical examination finding in 1.	11 (5/46) -SIJ pain in 3, flushing, shortness of breath after injection in 1, worsening SIJ pain related to physical therapy in 1.
Revision surgery*	3 (3/102)	

*Impingement of the implant on a sacral nerve root needed immediate revision (persistent pain resolved on repositioning) =1

*hairline fracture of the ilium adjacent to the caudal most implant causing buttock pain 18 months after procedure (possibly due to lifting heavy object), resolved with revision surgery by removing implants and inserting another implant and bone grafting of the joint, patient developed S1 radiculopathy which required further revision=1

*Contralateral SIJ pain (related to suboptimal placement of device) =1

Another patient in the crossover group (n=35) needed revision surgery for postoperative radicular pain, implant was repositioned.

Opioid use

	MI SIJF % (n=102)	NSM % (n=46)	Cross over (n=35)
Baseline	68.6	63	
6 months	58.4	70.5	
24 months	48.3		55.9

Abbreviations used: EQ-5D, EuroQol-5D; MI SIJF, minimally invasive sacroiliac joint fusion; NSM, non-surgical management; ODI, Oswestry Disability Index; PCI, posterior credible interval; PCS, physical component summary;SF-36, Short form-36; VAS, visual analogue scale.

Study 2 Sturesson B (2016)

Details

Study type	Randomised controlled trial
Country	Europe -4 countries: Belgium, Germany, Italy, Sweden (multicentre)
Recruitment period	2013-15
Study population and number	n=**103** patients with chronic SIJ pain **(52 minimally invasive SIJ fusion [MI SIJF] group versus 51 conservative management [CM] group).** Condition: SIJ pain unrelated to trauma or inflammatory disease (bilateral SIJ pain in 18) Prior lumbar fusion: 36% (37/103) Mean duration of pain: 4.7 years Prior treatments: steroid SIJ injection (73%), radiofrequency ablation (RFA, 16%)
Age and sex	mean age 48.1 years; 73% (75/103) women
Patient selection criteria	Adults with chronic disabling SIJ pain unrelated to acute trauma or underlying inflammatory disease, between 21-70 years, with low back pain for more than 6 months (18 months for pregnancy related pain) and diagnosed with SIJ pain as primary pain generator (based on pain close to posterior superior iliac spine and Fortin finger test, at least 3 findings on 5 physical examination manoeuvres for SIJ pain, 50% pain reduction on local anaesthetic into the joint), baseline ODI score of 30%, low back pain VAS score of 50 were included. Patients were excluded if they had severe low back pain due to other causes, autoimmune sacroilitis, recent pelvic trauma, spine surgery in the last 12 months, diagnosed or suspected osteoporosis and allergy to titanium.
Technique	**MI SIJF surgery** with triangular implants (iFuse Implant system) (typically 3) using a lateral approach under fluoroscopic guidance. Patients needing bilateral SIJ treatment had staged procedures. Only 39% (7/18) patients with bilateral SIJ pain had bilateral SIJF. Remaining patients had unilateral SIJF. **CM:** performed according to the European guidelines for diagnosis and management of pelvic girdle pain and consisted of optimisation of medical therapy, individualised physical therapy (twice per week for up to 8 weeks, mean 26.5 sessions) and adequate information and reassurance as part of a multifactorial treatment. Cognitive behaviour therapy was available at some sites. **Crossover:** CM patients crossed over to SIJF after the 6-month visit.
Follow-up	**6 months**
Conflict of interest/source of funding	Study was sponsored by the device manufacturer. Authors are investigators in SI-BONE clinical trials and paid consultants for the manufacturer.

Analysis

Follow-up issues: follow-up rates were high, 2 patients in CM group were lost to follow-up by 6 months (1 withdrew due to inability to tolerate to physical therapy).

Study design issues: prospective, multicentre, unblinded trial in 9 centres. Crossover design, randomisation was computer generated and stratified by site and pregnancy as a cause of SIJ pain in a 1:1 ratio (trial design similar to study in USA, Polly 2015). Data monitored and verified at all sites. Primary outcome was change in low back pain (LBP) visual analogue scale (VAS) score at 6 months. A modified intention to treat cohort was used for analysis. Secondary outcomes included improvement from baseline in LBP (using VAS scale), active straight leg raise test (ASLR) for the affected side, back dysfunction (using ODI), and quality of life score (as measured by EuroQol-5D compared with general population norms), self-rated satisfaction, walking distance and adverse events at 1, 3, and 6 months follow-up. Minimal clinically important differences were calculated for pain and ODI. No NSM subjects crossed over early. Both surgical and non-surgical groups received physical therapy. Conservative management does not include steroid injections and/or RF ablation and might have varied across centres.

Study population issues: baseline patient characteristics were similar between the 2 groups. Patients with other sources of low back pain have been included.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **103 (52 versus 51)**

Improvement in pain, disability, functional and quality of life scores

	MI SIJF (n=52)		**CM (n=51)**		**p value for comparison groups**
	Baseline	**6 months**	**Baseline**	**6 months**	
LBP score (VAS)^ mean	77.7	34.4 p<0.0001	73.0	67.8 p=0.1105	difference 38.1 points, p<0.0001
LBP score (VAS)^ by 20 points, %(n)		78.8% (41/52)		22.4% (11/51)	p<0.0001
ODI^^ score, mean	56.6	31.1 p<0.0001	56.6	50.8 p=0.0114	difference 19.8 points, p<0.0001
ODI^^ score by 15 points, % (n)		71.2% (/52)		24.5% (/51)	p<0.0001
SIJ functionality (ASLR)*	4.0	2.0	3.8	3.7	p<0.0001
ASLR % (n)		71.1%		32.0%	p=0.0002
Quality of life (EQ-5D TTO index)	0.30	change of 0.37 points	0.30	change of 0.11 points	difference 0.21 points, p<0.0001

^VAS 0-100mm, where 0 represents no pain and 100 represent the worst imaginable pain. ^^ ODI is a validated 10 question survey for disability from back pain.

*ASLR rating expressed on a scale 0-6.

Satisfaction

Satisfaction levels were higher at 3 and 6 months in the MI SIJF group compared to CM group (p<0.0001 by proportional odds logistic regression). The proportion of patients reporting they would have the procedure again was also high (p=0.0001). Improvement in self-reported walking distance (p=0.0111), global comparison to baseline was also higher (<0.0001) in the MI SIJF group.

Safety

Adverse events

	SIJF % (n=52)	**CM % (n=51)**	**p value**
Total	17 (9/52)10 events)	25 (13/51) 14 events)	0.0918
Severe adverse events	8 (**3 procedure related:** 2 postoperative hematomas, [1 needed surgical evacuation and 1 treated conservatively], 1 neural impingement causing pain related to incorrect device placement, resolved after revision surgery)	10	0.7868

Abbreviations used: ASLR, active straight leg raise test; EQ-5D, EuroQol-5D; LBP, low back pain; MI SIJF, minimally invasive sacroiliac joint fusion; CM, conservative management; ODI, Oswestry Disability Index; TTO, time trade-off index; VAS, visual analogue scale.

Study 3 Heiney J (2015)

Details

Study type	Systematic review and meta-analysis
Country	US
Study period	Search period: not reported; Databases searched: Embase and PubMed. In addition reviews and bibliographies of previously published systematic reviews were evaluated to identify articles not found in the search.
Study population and number	n=**12 unique cohort studies from 4 countries (432 patients** with degenerative sacroilitis or SIJ disruptions**) -1 randomised controlled trial, 3 prospective and 8 retrospective case series were included**.
Age and sex	Median 42 to 66 years; majority were women.
Study selection criteria	Articles in English, original prospective or retrospective studies with patients that described operative and clinical outcomes after Minimally invasive (MI) sacroiliac joint fusion (SIJF) using a lateral transarticular approach for SIJ dysfunction were included. Articles that report use of a dorsal distraction approach, open surgical technique, fusion of the pubic symphysis, single case reports, studies with no limited follow-up or clinical data, reports of traumatic pelvic injuries, ankylosing spondylitis, infection or tumour, studies on imaging were excluded.
Technique	MI SIJF using a lateral transarticular approach: 10 cohorts (n=368) used a series of triangular porous titanium plasma spray (TPS) coated implants (typically 3) (iFuse implant system) SI Bone) 2 cohorts (n=64, Mason 2013, Al Khayer 2008) used a hollow modular anchorage (HMA) screws packed with demineralised bone matrix (Aesculap Ltd).
Follow-up	**varied follow-up (range 6 -60months)**
Conflict of interest/source of funding	Review funded by (SI Bone Inc) manufacturer of implants using a transarticular approach. Two authors are employees of this company and one is a consultant.

Analysis

Follow-up issues: follow-up intervals varied across studies.

Study design issues: Systematic review and meta-analysis done according to Preferred Reporting Items for Systematic Reviews (PRISMA) guidelines. Significant variation was observed in many outcomes across studies and between the types of implants used. Random effects meta-analysis (RMA) was performed on selected variables using the DerSimonian and Laird method, including operative outcomes and patient reported outcome measures at several time points(e.g.: SI joint pain ratings on a visual analogue scale (VAS) (0-10 scale) and disability on the Oswestry Disability Index (ODI)). Mean and 95% confidence intervals (CI) were calculated and heterogeneity was assessed. Other findings (SF36 and Majeed scores reported in 2 studies and adverse events) were summarized qualitatively. Data quality assurance checks were done to ensure accuracy.

Majority of the studies included were industry sponsored.

Study population issues: patients were diagnosed using a common approach based on history, physical examination and diagnostic SI joint block.

Other issues: initially 18 studies were identified but after considering overlapping cohorts, 6 studies were (multiple publications of the same study) were excluded. The HMA screws used in 2 studies are not FDA cleared and not commercially available. There is some overlap with Zaidi 2015 systematic review.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **12 studies (n=432)**

Intraoperative outcomes

	RMA mean (range)
Mean procedure time (11 studies)	59 (range 27-78) minutes
Mean hospital length of stay	1.7 (0-7) days
Estimated blood loss	36.9 (10-70) ml

Pain and disability outcomes

	RMA mean (95% CI)				
	Baseline	**6 months**	**12 months**	**24 months**	**36 months**
Pain score (VAS 0-10)	**9 studies**	**4 studies**	**5 studies**	**2 studies**	**3 studies**
	8.1 [7.8-8.4]	2.8[2.4-3.2]	2.7 [2.1-3.3]	2.0[1.4-2.5]	3.7 [2.0-5.4]
ODI score (0-100%)	**8 studies**	**4 studies**	**5 studies**	**1 study**	**2 studies**
	56.6 [51.8-61.3]	30.3 [22.5-38.0]	25.1 [12.3-37.9]	-	30.4 [2.0-58.8]

^VAS 0-10, where 0 represents no pain and 10 represent the worst imaginable pain.
^^ODI is a validated 10 question survey for disability from back pain.

Quality of life (measured using SF-36)

	Baseline	**Follow-up**
SF-36 Physical component score (PCS)*		
Triangular implants (Duhon 2013)	30.2±6.2	42.8±10.0 (6 months)
Triangular implants (Whang 2006)	30.7±4.3	37±10.7 (6 months
HMA screw (Mason 2013)	26.6±15.2	43±22.68 (36 months)
Majeed score (used for grading outcome after pelvic fractures)		
HMA screw (Mason 2013)	36.18±15.08	64.78±20.18

*SF-36 is a 36 question, 8 subscale generic quality of life measure that summarises overall physical and mental health (PCS and MCS) with equivalent population norms. Higher scores indicate better health.

Safety

Adverse events	**Rate % (n)**
Total	**13 (57/432)**
Revision rate	**2.1 (9/432)**
Surgical wound problems	3.9 (17/432)
Trochanteric bursitis	1.9 (8/432)
Facet pain	0.7 (3/432)
Recurrent SI pain	0.7 (3/432)
Toe/foot numbness	0.5 (2/432)
Nerve root impingement needing revision	2.1 (9/432)
Iliac fracture	(1)
Hairline ilium fracture at caudal implant	(1)
Pulmonary embolism	(1)
Transient post-operative radiculopathic pain	(3)
Buttock pain	(1)
Low back pain	(2)
Piriformis syndrome	(3)
Leg pain	(1)
Bladder incontinence	(1)
Death	(0)

Abbreviations used: CI, confidence interval; HMA screw, hollow modular anchorage screw; ODI, Oswestry Disability Index; RMA, random effects meta-analysis; SF-36, short form-36; VAS, visual analogue scale;

Study 4 Zaidi HA (2015)

Details

Study type	Systematic review
Country	US
Study period	Search period: 2000-14; Databases searched: Medline, Google Scholar and OvidSP-Wolters Kluwer Health for all.
Study population and number	n=**9 studies (299** patients who had minimally invasive (MI) sacroiliac joint fusion (SIJF)). **(4 retrospective reviews, 3 prospective cohort studies, 2 consecutive case series)** Pathology: SIJ degeneration (n=15), chronic SIJ pain (n=22), degenerative sacroilitis or SIJ disruption (n=224) and sacral insufficiency fractures in cancer patients (n=6).
Age and sex	not reported
Study selection criteria	Peer reviewed, prospective or retrospective studies with at least 2 patients were included. Studies with follow-up shorter than 1-year, nonsurgical treatment, inadequate clinical data, non-English studies and non-human subjects were excluded.
Technique	MI SIJF surgery: procedures included use of triangular implants (iFuse implant system) in 5 studies; hollow modular anchorage (HMA) screws with autograft and bone morphogenetic protein (BMP) in 2 studies; multiple long screws crossing both SI joints & engaging the iliac bones in 1 study; 2 longitudinal threaded cages with BMP in 1 study.
Follow-up	**mean 21 months (range 6-70 months) for MI SIJF**
Conflict of interest/source of funding	One author is a consultant for Medtronic and DePuy Spine and receives royalties.

Analysis

Follow-up issues: varied follow-up periods in studies ranging from 6 to 40 months.

Study design issues: studies were reviewed by 2 independent investigators. Fusion was determined by CT or plain radiograph and clinical and patient scores were determined by subjective questionnaires and pain improvement scales.

Study population issues: 63% (201/430) of patients had some form of low back surgery before MI SIJF.

Other issues: evidence from 8 studies with open surgery for SIJF (n=131) in this systematic review was excluded as it is out of the scope of this overview. There is some overlap with Heiney 2015 systematic review.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **299**

Clinical and patient outcomes

Study	Assessment tools	Fusion rate % (n)	Non-union rate	Patient satisfaction	Reoperation rate %
Al-Khayer 2008	ODI, VAS, radiograph	100 (9/9) on plain radiograph	0	score 6.8/10	-
Wise & Dall 2008	Radiograph, VAS	89 (17/19)	11 (2/19)	77% (10/13) satisfied	5
Khurana 2009	SF-36, Majeed scoring system	13 (2/15) CT confirmation		87% (13/15) satisfied	
Papanastassiou 2011	KPS, 10 point pain scale			median pain relief 5.6 points	17
Rudolf 2012	SF-36, ODI, NRS 1-10	95% (52/55) CT bone ingrowth		81% (22/27) satisfied at 24 months.	8
Cummings & Capobianco 2013	VAS, ODI, SF-12			56% (10/18) very satisfied, 39% (7/18) somewhat satisfied, 11% (2/18) would not have procedure again.	6
Duhon 2013	VAS, ODI, SF-36, EQ-5D			85% (22/26) satisfied	0
Sachs & Capobianco 2013	Pain NRS, yes/no satisfaction			100% (40/40)	0
Ledino 2014	ODI			73% (16/22) satisfied.	9

Safety

Complications

Complication	% (n)
New-onset facet joint pain	2.7 (8/299)
Trochanteric bursitis	2.3 (7/299)
Deep wound infection	1.7 (5/299)
New onset low-back/buttocks pain	1.7 (5/299)
Worsening leg/knee pain	1.7 (5/299)
Superficial cellulitis	1.3 (4/299)
Radiculopathy	1.0 (3/299)
Large hematomas	1.0 (3/299)
Vascular necrosis of the hip	0.7 (2/299)
Piriformis syndrome	0.7 (2/299)
Implant penetration into sacral neural foramen	0.7 (2/299)
Peripheral neuropathy	0.3 (1/299)
Nondisplaced fracture	0.3 (1/299)
Pulmonary embolism	0.3 (1/299)
Deep vein thrombosis	0.3 (1/299)

Abbreviations used: EQ-5D, EuroQol-5 dimensions; HMA screw, hollow modular anchorage screw; KPS, Karnofsky performance status; NRS, numerical rating scale; ODI, Oswestry Disability Index; RMA, random effects meta-analysis; SF-36, short form-36; VAS, visual analogue scale;

Study 5 Duhon BS (2016)

Details

Study type	Case series (prospective cohort study)
Country	US (multicentre)
Study period	2012-13
Study population and number	n=**172** patients with SIJ pain due to degeneration or disruption of the SI joint. Condition: degenerative sacroilitis 78.5% (135/172); SI joint disruption 21.5% (37/172) Prior lumbar fusion: 44% (76/172) Mean duration of pain: 5.1 years Prior treatments: physical therapy 64.5% (111/172), steroid SI joint injections 94.2% (162/172), radiofrequency ablation 15.7% (27/172), opioid medications 76.2% (131/172).
Age and sex	mean age 50.9 years; 70% (120/172) women
Study selection criteria	Adults (21-70 years) patients with low back pain (LBP) for at least 6 months and unresponsive to conservative treatment, SI joint pain score of at least 50 points on a visual analogue scale (VAS), an Oswestry Disability Index (ODI) score of at least 30% and SI joint dysfunction due to degenerative sacroilitis or sacroiliac joint disruption (diagnosed based on a history of pain at or near the SI joint close to posterior superior iliac spine and Fortin finger test, 3 physical examination tests and at least a 50% decrease in pain after after injection of local anaesthetic into affected SI joint) and those with signed consent, metal and physical capacity to comply with study were included. Patients were excluded if they had severe LBP due to other causes, other known sacroiliac pathology, recent pelvic trauma, diagnosed or suspected osteoporosis, rheumatologic condition, chondropathy, allergy to titanium, medications that impair bone quality, neurologic conditions that interfere with physical therapy, infections, pregnancy, drug abuse, psychiatric conditions, receiving or seeking worker's compensation, disability remuneration, and/or involved in injury litigation.
Technique	**Minimally invasive (MI) SIJ fusion surgery** with triangular implants (iFuse Implant system) using a lateral approach under fluoroscopic guidance. 84% (144/172) had 3 implants, 13% (12/172) had 4 implants, 3.5% (6/172) had 2 implants. 8% (14/172) patients had bilateral SI joint fusion (same day or staged surgery within 60 days of first). Patients had individualised physical therapy twice a week for 6 weeks.
Follow-up	**24 months**
Conflict of interest/source of funding	Study was sponsored by the device manufacturer. Authors are investigators in SI-BONE clinical trials and paid consultants for the manufacturer. One author is an employee of SI-BONE.

Analysis

Follow-up issues: 97% (167/172) of patients had 6 month follow-up, 91% (157/172) had 12-month follow-up, 87% (149/172) had 24-month follow-up. At 24 months, 5 patients had withdrawn consent, 2 died from causes unrelated to the SI joint, 10 were lost to follow-up and 5 were unavailable for other reasons.

Study design issues: prospective single arm study in 26 sites. Data was monitored and verified at all sites. Primary outcome was success rate; secondary outcomes included improvement from baseline in SI joint and back pain (using VAS scale), back dysfunction (using ODI), quality of life scores (as measured by EuroQol-5D and SF-36 PCS), patient satisfaction. These were assessed at 1, 3, 6, 12, 18 and 24 months follow-up. A pelvic CT scan was done at 1 year and adverse events (defined according to an international clinical trial standard) were collected throughout follow-up. An intention to treat approach was used.

Study population issues: 24% (42/172) patients had lumbar stenosis and 14% (24/172) patients had hip diagnosis.

Other issues: Capobianco 2015 (study 6 in table 2) is a subgroup analysis of the same study.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **172**

Success rate~

	MI SIJF % (n=172)	**Bayesian posterior probability of superiority**
Intention to treat success rate	80.2 (/138) 95% PCI 73.8-85.7	>0.9999
12 month success rate	79.9 (127/159)	>0.9999
24 month success rate	79.9 (119/149)	>0.9999

~defined as composite endpoint of reduction from baseline in VAS back pain score by at least 20 mm, lack of device-related serious adverse events, absence of neurologic worsening and absence of surgical re-intervention.

Safety

Adverse events

	% (n)
Total	454 events (n=153)
Severe adverse events	n=73
Device related	**1.5 (7/454)**
Definite (neuropathic pain related to suboptimal implant placement in 3, SI joint pain after fall associated with inadequate device placement in1)	2.6 (4/153)
Probable (SI joint or buttock pain in 2, hip pain related to periosteal bone growth around the implant in1)	2.0 (3/153)
Procedure related (definite or probable)	**6 (26/454)**
Wound infection/drainage/irritation (1 needed surgical debridement)	6
SI joint pain	8
Wound numbness	1
Urinary retention	1
Postoperative nausea/vomiting needing prolonged hospitalisation	3
Vascular injury	1
Buttock pain	2
SI joint pain related to recurrent SI joint pain and suboptimal device placement requiring revision surgery	3
Foot weakness related to anaesthesia	1
Recurrent SIJ pain either due to S1 screw touching the proximal SI joint implant or additional stress to SI joint after lumbar fusion, revision surgery done – caudal implant removed and an additional triangular implant was placed across the joint in1).	4.7(8)

Improvement in pain and quality of life outcomes

	Mean (SD)	Improvement from baseline, mean (SD)	P value
LBP score (VAS)^			
Baseline	79.8 (12.8)		<0.001 for change from baseline
6 months	30.0 (26.5)	49.9 (28.3)	
12 months	30.4 (27.6)	49.3 (29.5)	
24 months	26.0 (26.7)	53.3 (27.6)	
ODI^^ score			
Baseline	55.2 (11.5)		<0.001
6 months	32.5 (19.7)	22.7 (20.6)	
12 months	31.5 (19.2)	23.8 (20.6)	
24 months	30.9 (20.5)	24.5 (21.1)	
SF-36 PCS**			
Baseline	31.7 (5.6)		<0.001
6 months	40.1 (9.6)	8.3 (9.7)	
12 months	40.5 (9.6)	8.8 (9.8)	
24 months	40.7 (10.3)	8.9 (10.6)	
SF-36 MCS**			
Baseline	38.5 (11.3)		<0.001
6 months	47.8 (11.6)	9.3 (12.7)	
12 months	48.2 (12.3)	9.5 (11.8)	
24 months	49.0 (11.5)	10.1 (11.8)	
EQ-5D TTO*			
Baseline	0.43 (0.18)		<0.001
6 months	0.69 (0.21)	0.25 (0.24)	
12 months	0.71 (0.20)	0.27 (0.24)	
24 months	0.71 (0.22)	0.27 (0.26)	

^VAS 0-100mm, where 0 represents no pain and 100 represent the worst imaginable pain. ^^ ODI is a validated 10 question survey for disability from back pain

*EQ-5D is a 5 question broad quality of life measure combined into a single index and represents TTO utility of current health.

** SF-36 is a 36 question, 8 subscale generic quality of life measure that summarises overall physical and mental health (PCS and MCS) with equivalent population norms.

The proportion of patients with VAS SIJ pain >20 points at 6, 12 and 24 months were 82.2%, 81.8% and 83.9%. The proportion having ODI >15 points were 65.7%, 66.7% and 69.1%.

Satisfaction rates: 78.1% of patients were very satisfied by 24 months and 93.8% were very or somewhat satisfied. 75% patients indicated that they would probably or definitely have the procedure again.

Other outcomes

Improvements were also seen in self-rated global assessments of pain and limitations in activities of daily living. The proportion of patients not working due to back pain decreased. Full ambulatory status was preserved in the majority of patients. The proportion of patients taking opioids for SIJ or low back pain decreased from 76.2% at baseline to 55.0%at months (p<0.0001).

Imaging results at 12 months (n=159) CT scan at 1 year showed 97% of adherence of bone (covering> 30% of the surface area of the implant) to at least 2 implants on both the iliac and sacral sides with moderate rates of bone growth across the SI joint. Radiolucency was seen in 17 patients, and the degree of lucency was <15% in most cases and typically seen when the distal end of the implant was <1cm into the sacrum. No device failure or migration was seen. Adverse bone reaction was absent, small cystic changes or erosions were seen in 9 cases. Bone remodelling was seen in >80% of treated SI joints. Bone bridging was seen in 39 cases either adjacent to or distant from implants	
Abbreviations used: EQ-5D, EuroQol-5 dimensions; LBP, low back pain; MCS, mental health component summary; MI SIJF, minimally invasive sacroiliac joint fusion; ODI, Oswestry Disability Index; PCI, posterior credible interval; PCS, physical health component summary; SD, standard deviation; TTO, time trade-off index; VAS, visual analogue scale.	

Study 6 Capobianco R (2015)

Details

Study type	Case series (prospective cohort study)
Country	US (multicentre)
Study period	2012-13
Study population and number	n=**172** patients with degenerative sacroilitis and/or sacroiliac joint (SIJ) disruptions. **(20 women with postpartum posterior pelvic girdle pain (PPGP), 100 women with no PPGP, 52 men)** Condition: degenerative sacroilitis 78.5% (135/172); SIJ disruption 21.5% (37/172) Prior lumbar fusion: 44% (76/172) Mean duration of pain: 5.1 years Prior treatments: physical therapy 64.5% (111/172), steroid SIJ injections 94.2% (162/172), radiofrequency ablation 15.7% (27/172), opioid medications 76.2% (131/172).
Age and sex	mean age 50.9 years; 70% (120/172) women
Study selection criteria	Adults (21-70 years) patients with low back pain (LBP) for at least 6 months and unresponsive to conservative treatment, SIJ pain score of at least 50 points on a visual analogue scale (VAS), an Oswestry Disability Index (ODI) score of at least 30% and SIJ dysfunction due to degenerative sacroilitis or SIJ disruption (diagnosed based on a history of pain at or near the SI joint close to posterior superior iliac spine and Fortin finger test, 3 physical examination tests and at least a 50% decrease in pain after after injection of local anesthetic into affected SIJ) and those with signed consent, metal and physical capacity to comply with study were included. Patients were excluded if they had severe LBP due to other causes, other known sacroiliac pathology, recent pelvic trauma, diagnosed or suspected osteoporosis, rheumatologic condition, chondropathy, allergy to titanium, medications that impair bone quality, neurologic conditions that interferes with physical therapy, infections, pregnancy, drug abuse, psychiatric conditions, receiving or seeking worker's compensation, disability remuneration, and/or involved in injury litigation.
Technique	**Minimally invasive (MI) SIJ fusion surgery** with triangular implants (iFuse Implant system) using a lateral approach under fluoroscopic guidance. 84% (144/172) had 3 implants, 13% (12/172) had 4 implants, 3.5% (6/172) had 2 implants. 8% (14/172) patients had bilateral SIJ fusion. (same day or staged surgery within 60 days of first). Patients had individualised physical therapy twice a week for 6 weeks.
Follow-up	**12 months**
Conflict of interest/source of funding	Study was sponsored by the device manufacturer. Authors are investigators in SI-BONE clinical trials and paid consultants for the manufacturer. One author is an employee of SI-BONE.

Analysis

Study design issues: prospective single arm study in 26 sites. Data was monitored and verified at all sites. Primary outcome was success rate, secondary outcomes included improvement from baseline in SIJ and back pain (using VAS scale), back dysfunction (using ODI) and quality of life scores (as measured by EuroQol-5D and SF-36 PCS). These were assessed at 1, 3, 6 and 12 months follow-up. Adverse events (defined according to an international clinical trial standard) were collected throughout follow-up. An intention to treat approach was used.

Study population issues: number of patients in PPGP group was very low and significantly younger (43 years versus 52.8 for women without PPGP and 50.5 for women, p=0.002). There were no differences in any demographic and clinical measures.

Other issues: This study is a subgroup analysis of Duhon 2016 (study 5 in table 2).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **172**

Success rate~

	Women with PPGP % (n=20)	Women with no PPGP % (n=100)	Men % (n=50)
Success at 6 months	94.7 (18/19)	78.0% (78/100)	80.0% (40/50)
Success at 12 months	76.5 (13/17)	77.9% (74/95)	82.6% (38/46)

~defined as composite endpoint of reduction from baseline in VAS back pain score by at least 20 mm, lack of device-related serious adverse events, absence of neurologic worsening and absence of surgical re-intervention.

Improvement in pain and quality of life outcomes

	Women with PPGP % (n=20)	Women with no PPGP % (n=100)	Men % (n=50)
LBP score (VAS)^, mean (SD)			
Baseline	81.9 (10.0)	79.9 (13.3)	78.9 (12.9)
6 months	21.3 (17.6)	31.5 (27.0)	30.2 (28.0)
12 months	31.4 (30.9)	32.7 (28.5)	25.0 (24.0)
12 months change	-51.1 (32.6)	-46.9 (29.9)	-52.9 (27.5)
>20mm decrease	94.7% (18/20)	78% (78/100)	80% (40/50)
change from baseline (p=.3708)	p<0.0001	p<0.0001	p<0.0001
ODI^^ score, mean (SD)			
Baseline	52.2 (12.7)	55.0 (11.2)	56.7 (11.5)
6 months	30.4 (20.0)	31.0 (18.7)	36.4 (21.4)
12 months	32.8 (21.4)	30.8 (19.1)	31.9 (18.9)
12 months change	-20.6 (26.0)	-24.1 (19.5)	-24.6 (21.0)
change from baseline (p=.3100)	p<0.0001	p<0.0001	p<0.0001
SF-36 PCS, mean (SD)**			
Baseline	32.0 (5.6)	31.1 (5.6)	32.7 (5.5)
6 months	40.0 (11.1)	40.5 (9.2)	39.8 (10.1)
12 months	41.6 (10.8)	40.0 (9.6)	40.5 (8.9)
12 months change	10.4 (10.1)	8.7 (9.9)	8.1 (9.8)
Change from baseline (p=.3623)	p<0.0001	p<0.0001	p<0.0001

Safety

Adverse events at 12 months

	PPGP % (n=20)	No PPGP % (n=100)	Men% (n=50)	All % (n=172)
Total events	n=37	n=158	n=88	
Related to device/procedure	4	10	7	
Wound infection	2		2	
Buttock pain	0	2	1	
Post-operative neuropathy	0	1	1	
nausea/vomiting	0	3	0	
SIJ pain	0	0	2	
intraoperative haemorrhage	0	1	0	
wound numbness	1	0	0	
Neuropathy after joint fusion	0	1	0	
Staple irritation	0	0	1	
Urinary retention	0	1	0	
wound drainage	0	1	0	
Fall causing SIJ pain^	1	0	0	
Revision rate	5% (1/20)^	2% (2/100)*	1.9% (1/50)**	2.3 (4/172)

^1 patient had pain due to fall and poor device placement, revision surgery done and additional implant place, pain resolved.

*2 revisions were immediate, to retract an implant that had violated the sacral neural foramen, resulting in nerve impingement.

** 1 patient had pain at 4 months, as a result of malposition (implant not across the joint), revision surgery done and implant replaced and an additional implant was placed.

SF-36 MCS, mean (SD)**			
Baseline	42.2 (12.4)	37.7 (11.6)	38.6 (10.3)
6 months	49.7 (9.6)	48.8 (10.8)	45.1 (13.2)
12 months	49.0 (10.8)	47.7 (12.9)	48.0 (12.1)
12 months change	7.2 (12.0)	10.2 (11.9)	8.2 (11.2)
Change from baseline (p=.1313)	p<0.0001	p<0.0001	p<0.0001
EQ-5D TTO*, mean (SD)			
Baseline	0.42 (0.14)	0.43 (0.18)	0.45 (0.19)
6 months	0.72 (0.23)	0.70 (0.19)	0.64 (0.25)
12 months	0.72 (0.21)	0.70 (0.20)	0.72 (0.19)
12 months change	0.31 (0.29)	0.27 (0.24)	0.26 (0.24)
Change from baseline (p=.0446)	p<0.0001	p<0.0001	p<0.0001
Satisfaction at 12 months % (n)			
Very or somewhat satisfied	100% (17/17)	84% (79/95)	91.3% (42/46)
No	0	16% (15/95)	8.7% (4/46)
Would have procedure again –yes	94.1% (16/17)	89.4% (84/94)	93.5% (43/46)
No	5.9% (1/17)	10.6% (10/94)	6.5% (3/46)

^VAS 0-100mm, where 0 represents no pain and 100 represent the worst imaginable pain. ^^ ODI is a validated 10 question survey for disability from back pain

*EQ-5D is a 5 question broad quality of life measure combined into a single index and represents TTO utility of current health.

** SF-36 is a 36 question, 8 subscale generic quality of life measure that summarises overall physical and mental health (PCS and MCS) with equivalent population norms.

Abbreviations used: EQ-5D, EuroQol-5 dimensions; LBP, low back pain; MCS, mental health component summary; MI SIJF, minimally invasive sacroiliac joint fusion; ODI, Oswestry Disability Index; PCS, physical health component summary; PPGP, postpartum posterior pelvic girdle pain; TTO, time trade-off index; VAS, visual analogue scale.

Study 7 Sachs D (2016)

Details

Study type	Case series (retrospective cohort study with prospective evaluation)
Country	USA (multicentre)
Study period	2012-13
Study population and number	n=**107** patients with degenerative sacroilitis and/or sacroiliac joint (SIJ) disruptions**.** Prior lumbar fusion: 36.4% Mean duration of SIJ pain: 5.9 years Prior treatments: physical therapy 62% (66/107), steroid SIJ injection 64% (69/107), radiofrequency ablation 16.8% (18/107). History of sacral trauma:32.7 % (35/107)
Age and sex	Mean age 57.5 years; sex: not reported.
Study selection criteria	Adults (at least of age 21 years) who had SIJ fusion using triangular implants (iFuse Implant System) prior to December 2012, whose charts documented preoperative pain scores, and who provided consent to complete questionnaires. diagnosis at all sites was made on the basis of history (buttocks pain with optional radiation into the groin or upper leg), typical pain reproduced on at least three physical examination manoeuvres, and a confirmatory diagnostic anaesthetic block of the SIJ producing acute pain relief.
Technique	**Minimally invasive (MI) SIJ fusion surgery** with triangular implants (iFuse Implant system) for all patients was performed through a transiliac, lateral muscle-sparing approach. 2.8% had bilateral procedures.
Follow-up	**mean 3.7 years**
Conflict of interest/source of funding	Study was sponsored by the device manufacturer. Authors are investigators in SI-BONE clinical trials and paid consultants for the manufacturer. One author is an employee of SI-BONE.

Analysis

Follow-up issues: some patients did not participate in prospective follow-up.

Study design issues: retrospective study with prospective evaluation in 7 centres. Patients were paid for participating in the study. Patients were contacted over phone or through email. Participants completed questionnaires in clinic, over phone or by email, regarding SIJ pain, activities related to SIJ dysfunction, and the Oswestry Disability Index (baseline scores not available). Charts were reviewed to extract baseline parameters and the clinical course of follow-up.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **107**

SIJ pain (numeric rating scale 1-10)	**Mean (SD)**
Baseline	7.5 (1.7)
Follow-up	2.6 (2.7)
Change score	-4.8 (2.9), p<0.0001
Follow-up ODI score^	**28.2(21.3)**
Satisfaction rate %	**87.9**
Patients would have procedure again %	83.2

^ODI is a validated 10 question survey for disability from back pain.

Ability to perform daily activities of living

The ability to perform activities commonly impaired by SIJ dysfunction showed positive improvements in most patients.

Additional and bilateral procedures

25.2% of patients had additional non-SIJ-related lumbar spine or hip surgeries during follow-up.

14 patients (13.1%) had contralateral SIJ fusion procedures during follow-up.

Safety

Adverse events

	% (n)
Mild ileus	(1)
Suture extending from wound	(1)
Adhesive tape allergic reaction	(1)
Revision surgeries* 1 at 41 days for early postoperative neuropathic pain related to implant malposition 1 at 18 months for recurrent pain possibly due to loosening of the uppermost implant and inadequate placement of the second implant 1 at 6 months for recurrent pain due to posterior placement of third implant, revision done through open approach and placement of bone graft. 1 at 3.3 years for little improvement due to inadequate placement of caudal implant. Patient also had L5-S1 lumbar decompression with fusion and pedicle screw for lumbar pain 1 at 9 months after an accident, patient had contralateral SIJF with further implants and a T9 laminotomy and placement of spinal cord stimulator.	**4.7 (5)**

*treatment outcomes were not reported in study.

Abbreviations used: SIJ, sacroiliac joint; ODI, Oswestry Disability Index.

Study 8 Miller LE (2015)

Details

Study type	Case series (prospective cohort study)
Country	USA and Europe (multicentre)
Study period	2009-13
Study population and number	n=**5,319** patients with degenerative sacroilitis and/or SIJ disruptions. **(USA n=4,962, Europe n=357)** Condition: degenerative sacroilitis and SIJ disruptions.
Age and sex	not reported
Study selection criteria	not reported
Technique	**Minimally invasive (MI) SIJ fusion surgery** with triangular implants (iFuse Implant system) (typically 3 or 4) using a lateral approach under fluoroscopic guidance. Procedures were performed by 487 physicians and 16,000 implants were used.
Follow-up	**4 years**
Conflict of interest/source of funding	Study was sponsored by the device manufacturer. Authors declare no other interests.

Analysis

Study design issues: prospective FDA mandatory ongoing post market surveillance database recording all spontaneous complaints in patients treated with triangular implants. Complaints recorded included revision surgery, pain, device related events, procedure related events and manufacturing related events. All complaints were reviewed by a team from the manufacturer before entry into database. Data was analysed by independent authors. Large numbers of patients were included.

Key safety findings

Safety

Number of patients analysed: **5319**

	% (n=5319)
Patients with complaints (median time 5 months after surgery. 43% within 90 days, 30% between 90 days to 1 year, 21% between 1 and 2 years, 6% beyond 2 years).	**3.8 (204/5319)**
Clinical events	
Any pain (14% within 30 days, 9% between 31-90 days, 43% between 91-365 days, 34% at 1 year)	2.2 (119/5319)
Nerve impingement	n=48
Recurrent sacroiliac joint pain	43
Unknown cause	18
Neuropathic pain	13
Inadequate pain relief	12
Malalignment	11
Piriformis syndrome	7
Local soft tissue pain	5
Haematoma/excessive bleeding	0.2 (11)
Iliac fracture	<0.1 (4)
Superficial wound infection	<0.1 (3)
Deep vein thrombosis	<0.1 (2)
Device related events	**1.3 (75)**
Pin bind/bend/break	0.8 (43)
Pin advancement	0.3 (14)
Radiographic halo	0.2 (13)
Migration	<0.1 (4)
Procedure related events	**2.1 (108)**
Any improper device placement (Medial 20, anterior 18, dorsal 14, cephalad 12, proud 8, inferior 2, other malposition 2)	1.4 (72)
Any improper device size (too short 30, too long 7)	0.7 (36)

There were no pulmonary embolisms, vascular injury, gastrointestinal injury, sacral fracture or deaths reported.

Revisions (at a median of 4 months)	**1.8% (n=96/5319)**
Early (at median 19 days)	**58 (56/96)**
Malposition, symptomatic (nerve impingement 19, Piriformis syndrome 17, local soft tissue pain 13)	48 (46/96)
Malposition, asymptomatic (nerve impingement 9, Piriformis syndrome 2, local soft tissue pain 1)	10 (10/96)
Late (median 297 days)	**42 (40/96)**
Symptom recurrence (explant only 15, additional implant only 13, unknown 6, device adjustment only 3, explant and reimplant 3)	35 (34/96)
Supplemental fixation (lateral screws 15, none 14, posterior fixation 3, anterior fixation 2)	n=34
Supplemental bone grafting (local lateral 17, none 9, open posterior 6, open anterior 2)	n=34
Continued pain of undetermined pathology (explant only 3, explant and reimplant 1, device adjustment 1, additional implant only 1, unknown 1)	6 (6/96)

Abbreviations used:

Study 9 Schoell K (2016)

Details

Study type	Case series (retrospective study)
Country	US
Study period	2007-14
Study population and number	n=**469** patients with degenerative sacroilitis and/or SIJ disruptions.
Age and sex	Age: range 15-94 years, 65% (305/469) women
Study selection criteria	Patients diagnosed with at least one of the 6 ICD-9 codes that indicate medical necessity for minimal invasive (MI) sacroiliac joint fusion (SIJF) before receiving a procedure billed by one of the two Current Procedural Terminology (CPT) codes were included. Patients who had open surgery, patients having SIJF with a previous diagnosis of pelvic ring fracture and pelvic neoplasms were excluded. Patients who previously received arthrodesis, SIJ, unlisted procedure for pelvis or spine were also excluded.
Technique	**MI SIJF surgery** with triangular implants (iFuse Implant system) (typically 3 or 4) using a lateral approach under fluoroscopic guidance.
Follow-up	**7 years**
Conflict of interest/source of funding	2 authors received consultancy fees and one author received royalties from different companies.

Analysis

Study design issues: retrospective analysis of a large sample using a nationwide (Humana) private insurer database. Billing codes and International Classification of Diseases (ICD-9) diagnosis codes were used to identify patients and data from patients' records were analysed to determine incidence of postoperative infection, pain, osteomyelitis, joint derangement, urinary tract infection and novel lumbar and nervous system pathology.

Key safety findings

Safety

Number of patients analysed: **469**

	Total % (n) (n=469)	**Women % (n) (n=305)**	**Men % (n) (n=164)**
Total complications within 90 days	13.2 (n=62)	16.1 (n=49)	7.9 (n=13) p<0.05
Total complications within 6 months	16.4 (n=77)	18.7 (n=57)	12.2 (n=20) p=0.07
Novel lumbar pathology* within 90 days	3.6 (n=17)	3.3 (n<10)	6.7 (n=11), p<0.1
Novel lumbar pathology within 6 months	5.3 (n=25)	3.3 (n<10)	9.1 (n=15) p<0.1
Infection at 90 days	3.6 (n=17)	5.1 (n=16)	n<11
Infection at 6 months	4.1 (n=19)	5.1 (n=16)	n<11
Nervous system at 90 days	4.3 (n=20)	4.8 (n=15)	n<11
Nervous system at 6 months	6.2 (n=29)	6.7 (n=21	n<11
Pain 90 days	2.6 (n=12)	n<11	n<11
pain at 6 months	4.1 (n=19)	4.6 (n=14)	n<11
Urinary tract infections at 90 days	3.8 (n=18)	4.9 (n=15)	n<11
Urinary tract injection 6 months	4.9 (n=23)	6.2 (n=19)	n<11
Osteomyelitis at 90 days and 6 months	n<11	n<11	n<11
Joint derangement at 90 days and 6 months	n<11	n<11	n<11

*disorders such as lumbar stenosis, displaced lumbar disc, lumbar disc disorder with myelopathy.

Abbreviations used:

Efficacy

Success rate (defined as a composite of pain reduction from baseline in visual analogue scale [VAS] pain score by at least 20 mm, absence of device-related serious adverse events or neurologic worsening and absence of surgical re-intervention)

In a randomised controlled trial (RCT) of 148 patients with SI joint dysfunction comparing minimally invasive SI joint fusion (n=102) with non-surgical management (NSM, n=46), success rates at 6 months were higher in the minimally invasive SI joint fusion group (81% [83/102] versus 26% [12/46]; Bayesian posterior probability of superiority >0.9999)[1].

In a prospective case series of 172 patients with chronic SI joint dysfunction treated by minimally invasive SI joint fusion, intention-to-treat success rate was 80% (138/172) (95% posterior credible interval [PCI] 73.8-85.7) at 6 months, 80% (127/159) at 12 months and 80% (119/149) at 24 months; Bayesian posterior probability of superiority >0.9999 at all-time points[5].

Radiographically confirmed fusion rates

In a systematic review on SI joint fusion of 430 patients in those who had minimally invasive SI joint fusion (n=299), radiographically confirmed fusion rates (determined by CT or plain radiograph) were 13% to 100% (in 4 out of 9 studies) at a mean follow-up of 21 months[4].

In the prospective case series of 172 patients, CT scan at 1-year follow-up showed a high rate (97%) of bone adherence (covering more than 30% of the surface area of the implant) to at least 2 implants on both the iliac and sacral sides with moderate rates of bone growth across the SI joint[5].

Improvement in SI joint pain and back dysfunction

In the RCT of 148 patients, in the SI joint fusion group (n=102), mean SI joint pain (measured using a 0-100 visual analogue scale [VAS]) improved from 82.3 at baseline to 30.4 at 6 month follow-up (p<0.001), 28.3 at 12 month follow-up (p<0.001) and 26.7 at the 24 month follow-up (p<0.001). In the NSM group, mean SI joint pain improved from 82.2 at baseline to 70.3 at 6 months (p=0.001). Similarly, in the SI joint fusion group, mean Oswestry Disability Index (ODI) decreased from 57.2 at baseline to 29.9 at 6 months, 28.1 at 12 months (p<0.001) and 28.7 at 24 months (p<0.001). In the NSM group, mean ODI decreased from 56.0 at baseline to 51.6 at 6 months (p=0.06). Clinically important improvements from baseline at 12 months occurred in 82% of patients (based on a VAS score of more than 20 points) and 72% of patients (based on an ODI more than 15 points) in the SI joint fusion group compared with only 13% and 10% of patients in the NSM group[1]. By 24 months, in the SI joint fusion group, 83% and 82% received either clinical improvement (VAS >20 points) or

substantial clinical benefit (>25 or<35 points) in VAS SI joint pain score. Similarly, 68.2% and 65.9% had received clinical improvement (ODI more than15 points) or sustained clinical benefit (>18.8 points) in ODI score at 24 months. In NSM group these proportions were less than 10%. Patients who crossed over (n=35) had improvements in pain and disability similar to those in the original SI joint fusion group[1].

In an RCT of 103 patients with chronic SI joint pain, in the SI joint fusion group (n=52), mean low back pain (LBP) (measured using a 0 to 100 visual analogue scale [VAS]) improved from 77.7 at baseline to 34.4 at 6-month follow-up (p<0.0001). In the conservative management (CM) group, the mean LBP VAS improved from 73.0 at baseline to 67.8 at 6 months (p=0.1105), (difference of 38.1 points between the groups, p<0.0001). Similarly, in the SI joint fusion group, mean Oswestry Disability Index (ODI) decreased from 56.6 at baseline to 31.1 at 6 months (p<0.0001). In the CM group, mean ODI deceased from 56.6 at baseline to 50.8 at 6 months (p=0.0114).Clinically important improvements (from baseline VAS more than 20 points, ODI more than 15 points) at 6 months occurred in 79% and 71% of the SI joint fusion patients compared to only 22% and 25% of the CM patients (p<0.0001)[2].

In the systematic and meta-analysis of 432 patients from 12 cohort studies on minimally invasive SI joint fusion using a lateral transarticular approach, the random effects meta-analysis (RMA) mean pain score dropped by 5.3 points at 6 months and 5.4 points at 12 months (baseline score of 8.1 [7.8-8.4], 6-month score of 2.8 [2.4-3.2], 12-month score of 2.7 [2.1-3.3]), and a 24-month score of 2.0 (1.4-2.5). Significant heterogeneity was observed for the baseline, 12 and 36 month scores but not for the 6 or 24 month scores. ODI decreased by 31 points at 12 months (baseline score of 56.6 [51.0-61.5], 6-month score of 30.3 [22.5-38.0] and 12-month score of 25.1 [12.3-37.9]). Significant heterogeneity was observed for the baseline, 6- and 12-month scores[3].

In the prospective case series of 172 patients with chronic SI joint dysfunction treated by minimally invasive SI joint fusion, SI joint pain decreased from 79.8 at baseline to 30.4 at 12 months and remained low at 26.0 at 24 months (p<0.0001 for change from baseline). ODI decreased from 55.2 at baseline to 31.5 at 12 months and remained low at 30.9 at 24 months (p<0.0001 for change from baseline). The proportion of patients with VAS joint pain improvement of more than 20 points and ODI of more than 15 points at 24 months were 84% and 69% respectively[5]. A subgroup analysis of women with persistent post-partum posterior pelvic girdle pain (n=20) in the same study reported significant improvement in pain (-51mm on VAS) and function (-20.6 points on ODI scale) at 12 months[6].

SI joint function

In the RCT of 103 patients, SI joint function ratings (measured using the active straight leg raise test [ASLR] on a scale of 0 to 6) decreased from 4.0 to 2.0 in

the SI joint fusion group and from 3.8 to 3.7 in the CM group (p<0.0001). The proportion of patients who could raise the leg with no difficulty at 6 months was 71% in SI joint fusion group and 32% in CM group (p=0.0002)[2].

Improvements in quality of life

In the RCT of 148 patients, in the SI joint fusion group (n=102), quality of life (measured with an EQ-5D and represents time trade off (TTO) index utility of current health) improved from 0.44 at baseline to 0.72 at 6 month follow-up (mean change 0.29 points, p<0.001), 0.74 at 12 month follow-up (p<0.001) and 0.72 at the 24 month follow-up (p<0.001). The mean change was only 0.05 points in the NSM group at 6 months (p=0.17). For patients who crossed over (n=35), the change was small at 6 months (0.02; p=0.66), but after cross over, improved from 0.47 at 6 months to 0.73 at 12 months (0.26 point increase, p<0.001). In those who did not cross over (n=11), the change from 6 to 12 months was little (p=0.008). Quality of life (measured using SF-36) showed that mean 6-month changes in PCS and mental health component summary scores (MCS scores) were statistically significant (p<0.001) in the fusion group compared with the NSM group. Patients who crossed over from NSM after 6 months had larger improvements in PCS and MCS scores compared with those who did not cross over[1].

In the RCT of 103 patients, EQ-5D TTO index and VAS were depressed in both groups at baseline compared to general population. EQ-5D TTO improved more in the SI joint fusion group compared to the CM group [change of 0.37 points (p<0.0001) in SI joint fusion group, change of 0.11 points in CM group (p=0.0189), 0.21 point difference, p<0.0001]. Similarly, EQ-5D VAS improved more in the SI joint fusion group (20.2 points more improvement, p<0.0001)[2].

In the systematic and meta-analysis of 432 patients from 12 cohort studies on MI SI joint fusion using a lateral transarticular approach, improvements in quality of life (measured on the SF-36 physical component score [PCS]) were consistent in 2 studies of triangular implants; scores increased from 30.2 and 30.7 at baseline to 42.8 and 37.0 at 6 months, respectively. In 1 study with hollow modular anchorage (HMA) screws, a similar improvement was seen (from 26.6 at baseline to 43 at 36 months)[3].

In the systematic review and meta-analysis of 432 patients from 12 cohort studies on minimally invasive SI joint fusion using a lateral transarticular approach, Majeed score (used for grading the outcome after pelvic fractures) reported in 1 HMA screw study improved from 36.18 at baseline to 64.78 at 36 months follow-up[3].

In the prospective case series of 172 patients with chronic SI joint dysfunction treated by minimally invasive SI joint fusion, quality of life (measured using EQ-5D TTO index) improved from mean 0.43 at baseline to 0.71 at 12 months and sustained at 24 months. All SF-36 domains (PCS and MCS) improved at all time

points (PCS 31.7 at baseline to 40.5 at 12 months and 40.7 at 24 months, p<0.001; MCS 38.5 at baseline to 48.2 at 12 months and 49.0 at 24 months, p<0.001)[5]. A subgroup analysis of women with persistent post-partum posterior pelvic girdle pain (n=20) in the same study, reported significant improvement in quality of life (SF-36 PCS +10.4, MCS+7.2, EQ-5D +0.31) at 12 months[6].

Satisfaction

In the systematic review on SI joint fusion of 430 patients, clinical and patient satisfaction with surgery (determined by subjective questionnaires and judged by a patients' stated satisfaction with surgery) ranged from 56% to 100% in 299 patients (from 9 studies) who had minimally invasive SI joint fusion at a mean follow-up of 21 months[4].

In the RCT of 103 patients, satisfaction levels were higher at 3 and 6 months in the SI joint fusion group compared with the CM group (p<0.0001 by proportional odds logistic regression). The proportion of patients reporting that they would have the procedure again was also higher in the SI joint fusion group (p=0.0001). Improvement in self-reported walking distance (p=0.0111), global comparison to baseline were also higher (<0.0001) in the SI joint fusion group[2].

In the case series of 172 patients, satisfaction rates were high, with 94% reporting very or somewhat satisfied at 24 months. 75% of them indicated that they would definitely have the procedure again[5].

Safety

Overall complication rate

In a prospective database analysis of post-marketing complaints for patients having minimally invasive SI joint fusion for degenerative sacroiliitis and SI joint disruption, the overall complication rate was 4% (204/5,319). Pain was the most commonly reported event (2% [119/5,319]), followed by nerve impingement in less than 1% (48) and recurrent SI joint pain in less than 1% (n=43). Other clinical events reported rarely were significant operative bleeding or hematoma in 0.2% (n=11), iliac fracture, deep vein thrombosis, wound infection in less than 0.1% of patients[8].

In a systematic and meta-analysis of 432 patients from 12 cohort studies on minimally invasive SI joint fusion using a lateral transarticular approach, the overall complication rate was 13% (57/432). The most common events were surgical wound problems (4% 17/432), trochanteric bursitis (2% (8/432), facet pain (less than 1%, 3/432), recurrent SI pain (less than 1%, 3/432), toe and foot numbness (less than 1%, 2/432), and nerve root impingement needing revision in 2% (9/432) patients[3].

In a systematic review on SI joint fusion including 430 patients, for those having minimally invasive SI joint fusion (n=299, in 9 studies), major complications

ranged from 5 to 20%, with 1 study reporting a 56% adverse event rate. Complications reported were new-onset facet joint pain, trochanteric bursitis, deep wound infections, new onset of low back or buttock pain, superficial cellulitis, radiculopathy, vascular necrosis of the hip, piriformis syndrome, implant penetration into the sacral neural foramen, peripheral neuropathy, a nondisplaced fracture, pulmonary embolism, and deep vein thrombosis[4].

In a retrospective analysis of 469 patients treated by minimally invasive SI joint fusion, complication rate at 90 days was 13.2% (62/469) and 16.4% (77/469) at 6 months. The incidence of complications was 19% (57/305) for women and 12% (20/164) for men at 6 months (p=0.7)[9].

In a randomised controlled trial (RCT) of 148 patients, 179 adverse events were reported in the SI joint fusion group and 89 in the NSM group at 12-month follow-up. Of these 78 were severe adverse events. The mean number of adverse events were slightly higher in the SI joint fusion group compared to NSM group (1.8, [179 events] versus 1.9 [89 events]; p=0.45). Leg pain and pelvic pain were the most common events[1].

In an RCT of 103 patients, 10 adverse events were reported in SI joint fusion group and 14 in the CM group at 6 months follow-up. Of these, 18 were severe adverse events. The mean number of events were slightly smaller in the SI joint fusion group compared to CM group (17% (9/52), 10 events versus 25% (13/51), 14 events p=0.0918)[2].

Device related events

In the prospective database analysis of post-marketing complaints for patients having minimally invasive SI joint fusion, 1% (75/5319) the device-related adverse events were reported. These were related to issues with binding, bending or breakage of the Steinmann pin (n=43), pin advancement difficulties (n=14) and device migration (n=4) [8].

In the RCT of 148 patients, device related events were reported in 3% (3/102) the SI joint fusion group at 6 months follow-up. Two events (1 implant related impingement on a sacral nerve causing pain and needing immediate revision and 1 hair line ilium fracture adjacent to implant causing pain, resolved after revision surgery) were definitely related to the device and 1 event (SI joint pain because of suboptimal placement of implants, which needed revision surgery) was deemed probably related to the device[1].

Procedure related events

In the prospective database analysis of post-marketing complaints for patients having minimally invasive SI joint fusion, 2.1% (108/5,319) procedure related events were reported. Improper implant placement was reported in 1% (n=72) of patients, with medial (20), anterior (18), dorsal (14) and cephalad (12) placement in relation to correct anatomical location. Improper device length was reported in

less than 1% (n=36) of patients with most implants deemed to be too short (n=30)[8].

In the RCT of 148 patients, 19% (19/102) of the events were probably or definitely related to the SI joint fusion and 11% (5/46) of the events were related to NSM at 6-month follow-up. Events related to surgical procedure included neuropathic symptoms (n=1), postoperative medical problems (n=4; urinary retention, nausea/vomiting, atrial fibrillation), SI joint pain or trochanteric bursitis (n=7), surgical wound problems (n=5), iliac fracture (n=1) and asymptomatic physical examination finding (n=1). With NSM, 3 patients reported SI joint pain after treatment, 1 had flushing and shortness of breath after SI joint injection and 1 had worsening SI joint pain related to physiotherapy[1].

In an RCT of 103 patients, three procedure related adverse events (2 postoperative haematomas and neural impingement related to incorrect device placement causing radicular pain) were reported in SI joint fusion group (n=52) at a follow-up of 6 months. Revision surgery was done by pulling back the implant a few millimetres and pain resolved. One haematoma needed surgical evacuation and 1 was treated conservatively[2].

Reoperation rate

In the systematic review on SI joint fusion of 430 patients (in 9 studies), reoperation rate in the 299 patients who had minimally invasive SI joint fusion surgery ranged from 0% to 17% (mean 6%) at a mean follow-up of 21 months[4].

In the systematic review and meta-analysis of 432 patients from 12 cohort studies on minimally invasive SI joint fusion using a lateral transarticular approach, the revision rate was 2% (9/432)[3].

In the prospective database analysis of post-marketing complaints for patients having minimally invasive SI joint fusion, the reoperation rate was 2% (n=96/5,319) at a median follow-up of 4 months. Revisions were typically done in the early postoperative period (median 19 days) for treatment of a symptomatic wrongly positioned implant (less than 1%, n=46), or to correct an improperly sized implant in an asymptomatic patient (less than 1%, n=10). Revised wrongly positioned implants were most often placed too medial (20), anterior (15), or cephalad (10). Revised improperly sized implants were deemed to be too short and were subsequently explanted. Revisions in the late postoperative period were done (at a median of 297 days) to treat symptom recurrence (0.6%, n=34) or for continued pain of undetermined aetiology (0.1%, n=6). Revision outcomes and management of these patients were not reported[8].

In the RCT of 148 patients, reoperation rate was 3% (3/102) at 24 months' follow-up in the SI joint fusion group[5].

In the case series of 172 patients who had minimally invasive SI joint fusion surgery, reoperation rate was 4.7% (8/172) at 24 months follow-up[5].

Postoperative infection

Postoperative infection rate was 4% (n=19) at 6 months in a retrospective analysis of 469 patients treated by minimally invasive SI joint fusion[9].

Novel lumbar pathology

Novel lumbar pathology rate was 3.6% (n=17) at 90 days and 5.3% (n=25) at 6 months in a retrospective analysis of 469 patients treated by minimally invasive SI joint fusion. Men experienced higher rates than women within both 90 days (men 6.7%, women 3.3%) and 6 months (men 9%, women <3.3%) of the procedure ($p<0.1$)[9].

Validity and generalisability of the studies

- Several devices are available for minimally invasive SI joint fusion and there are differences in design and placement approaches.
- The majority of the published evidence reports the use of triangular titanium implants in a lateral transarticular approach (2 multicentre RCTs in the US and Europe[1-2], 2 prospective cohort studies[5,6,8], a systematic review[4] and a meta-analysis[3] of several cohort studies and 2 retrospective case series[7,9]). Two cohort studies included in the systematic reviews[3-4] report the use of hollow modular anchorage (HMA) screws through a dorsal approach.
- There is some overlap of studies between the 2 systematic reviews[3-4].
- Two RCTs compared minimally invasive SI joint fusion (with triangular implants) against non-surgical treatment for SI joint dysfunction[1-2].

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica. NICE interventional procedure guidance 544 (2016). Available from https://www.nice.org.uk/guidance/IPG544
- Percutaneous coblation of the intervertebral disc for lower back pain and sciatica. NICE interventional procedure guidance 543 (2016). Available from https://www.nice.org.uk/guidance/IPG5443
- Transaxial interbody lumbosacral fusion. NICE interventional procedure guidance 387 (2011). Available from https://www.nice.org.uk/guidance/IPG387
- Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedure guidance 366 (2010). Available from https://www.nice.org.uk/guidance/IPG366
- Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010). Available from http://www.nice.org.uk/guidance/IPG357
- Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedure guidance 321 (2009). Available from http://www.nice.org.uk/guidance/IPG321
- Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009). Available from http://www.nice.org.uk/guidance/IPG306
- Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009). Available from http://www.nice.org.uk/guidance/IPG300
- Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005). Available from http://www.nice.org.uk/guidance/IPG141
- Endoscopic laser foraminoplasty. NICE interventional procedure guidance 31 (2003). Available from http://www.nice.org.uk/guidance/IPG31

NICE guidelines

- Low back pain in adults: early management. NICE clinical guideline 88 (2009). 'This guidance is currently under review and is expected to be updated in 2016'. Available from http://www.nice.org.uk/guidance/CG88

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Two Specialist Advisor Questionnaires for minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme sent 15 questionnaires to 1 NHS trust for distribution to patients who had the procedure (or their carers).

Company engagement

A structured information request was sent to 2 companies who manufacture a potentially relevant device for use in this procedure. NICE received 2 completed submissions. These were considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- Ongoing studies
  - NCT02074761 Evolusion Study Using the Zyga Simmetry sacroiliac joint fusion system; study type: observational cohort; n=250; primary outcome: SI joint fusion; location: USA; study completion date December 2019.
  - NCT02560714 SI Joint Fusion and Decortication Using the SImmetry System; study type: observational cohort; n=25; primary outcome: SI joint fusion; location: USA; completion date: August 2019.

- NCT02270203 LOIS: Long-Term Follow-Up in INSITE/SIFI (LOIS); study type: observational cohort; n=225; primary outcome: improvement in SI joint pain; location: USA; completion date: January 2019.
- NCT01861899 Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation SI-SI-LOK; study type: observational case series; n=55; primary outcome: radiographic evaluation; location USA; completion date: August 2017.

References

1. Polly DW., Cher DJ, Wine KD et al (2016). Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. Neurosurgery (77) 5 674-90; discussion 690-1.
2. Sturesson B, Dengler J, Kools D et al (2016). Sacroiliac minimal invasive fusion compared to physical therapy: Sixmonth outcome from a multicentre randomised controlled trial. Spine Journal (1)) S73-S74.
3. Heiney J, Capobianco R and Cher D (2015). A systematic review of minimally invasive sacroiliac joint fusion utilizing a lateral transarticular technique. International Journal of Spine Surgery (9) 40
4. Zaidi HA., Montoure AJ and Dickman CA (2015). Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. Journal of Neurosurgery Spine (23) 1 59-66.
5. Duhon BS, Bitan, Fabien, Lockstadt, Harry, Kovalsky, Don, Cher, Daniel, Hillen, Travis and Group, Sifi Study (2016). Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-Year Follow-Up from a Prospective Multicenter Trial. International Journal of Spine Surgery (10) 13
6. Capobianco R, Cher D and Group, Sifi Study (2015). Safety and effectiveness of minimally invasive sacroiliac joint fusion in women with persistent post-partum posterior pelvic girdle pain: 12-month outcomes from a prospective, multi-center trial. Springerplus (4) 570
7. Sachs D, Kovalsky D et al (2016). Durable intermediate- to long-term outcomes after minimally invasive transiliac sacroiliac joint fusion using triangular titanium implants. Medical Devices Evidence and Research (9) 213–222.
8. Miller LE, Reckling W Carlton and Block JE (2013). Analysis of postmarket complaints database for the iFuse SI Joint Fusion System: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. Medical Devices Evidence and Research (6) 77-84.
9. Schoell K, Buser Z, Jakoi A et al (2016). Postoperative complications in patients undergoing minimally invasive sacroiliac fusion. The Spine Journal (article in press).

Appendix A: Additional papers on minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Al-Khayer A, Hegarty J et al (2008). Percutaneous sacroiliac joint arthrodesis: a novel technique. Journal of Spinal Disorders & Techniques (21) 5 359-63.	Retrospective case series n=8 patients with chronic SI joint pain treated by percutaneous sacroiliac joint arthrodesis technique utilizing a Hollow Modular Anchorage screw. Follow-up: mean 40 months (range 24-70)	The mean ODI value dropped from 59 (range: 34 to 70) preoperatively to 45 (range: 28 to 60) postoperatively (P<or=0.005). The mean VAS value dropped from 8.1 (range: 7 to 9) preoperatively to 4.6 (range: 3 to 7) postoperatively (P<or=0.002). The mean patients' satisfaction was 6.8 (range: 5 to 8).	Study included in systematic review (Heiney 2015) added to table 2.
Ashman B, Norvell DC. and Hermsmeyer, JT (2010). Chronic sacroiliac joint pain: fusion versus denervation as treatment options. Evidence based Spinecare Journal (1) 3 35-44	Systematic review compare the safety and effectiveness of fusion versus denervation for chronic sacroiliac joint pain after failed conservative management 11 studies (six fusion, five denervation) included.	The majority of patients report satisfaction after both treatments. Both treatments reported mean improvements in pain and functional outcome. Rates of complications were higher among fusion studies (13.7%) compared to denervation studies (7.3%). Only fusion studies reported infections (5.3%). No infections were reported among denervation patients. The evidence for all findings were very low to low; therefore, the relative efficacy or safety of one treatment over another cannot be established.	Studies on open surgery and MIS techniques were included to evaluate fusion for SI joint pain.

Cher DJ, Frasco MA et al (2016). Cost-effectiveness of minimally invasive sacroiliac joint fusion.[Clinicoeconomics & Outcomes Research. VOL 8 PP 1-14. Erratum appears in Clinicoecon Outcomes Res. 2016;8:305; PMID: 27445500]	Cost effectiveness analysis on SI joint fusion using triangular titanium implants.. Data from 2 clinical trials used for modelling.	SI joint fusion was associated with a gain of approximately 0.74 quality-adjusted life years (QALYs) at a cost of US$13,313 per QALY gained. In multiple one-way sensitivity analyses all scenarios resulted in an incremental cost-effectiveness ratio (ICER) ,$26,000/QALY. Probabilistic analyses showed a high degree of certainty that the maximum ICER for SI joint fusion was less than commonly selected thresholds for acceptability (mean ICER =$13,687, 95% confidence interval $5,162–$28,085). SI joint fusion provided potential cost savings per QALY gained compared to non-surgical treatment after a treatment horizon of greater than 13 years.	Cost effectiveness study. out of scope.
Cummings J Jr. and Capobianco RA (2013). Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. Annals of Surgical Innovation & Research [Electronic Resource] (7) 1 12	Retrospective case series n=18 patients refractory to conservative care had minimally invasive (MIS) SI joint arthrodesis using a series of triangular, titanium plasma spray (TPS) coated implants. Follow-up: 12 months	No intraoperative complications and 1 explant at 3months for malposition. All patient-reported outcomes showed both clinically and statistically significant improvement at 12 months ($p<0.001$ for each of the following): VAS improved by 6.6 points, ODI scores improved by -37.5 points. 1 year SF-12 physical and mental component (PCS, MCS) scores approximated population normal scores for both physical and mental functioning. Patient satisfaction with outcomes was high at 95%; 89% said would have the same surgery again.	Study included in systematic review (Heiney 2015) added to table 2.

Duhon BS, Cher DJ, Wine KD et al (2015) on behalf of the SIFI study group. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study. Global Spine Journal.6 (3) 257-69.	Prospective case series (cohort study) n=172 patients with SI joint degeneration or disruption who had minimally invasive fusion using the iFuse Implant System. Follow-up: 12 months	Mean SI joint pain improved from 79.8 at baseline to 30.0 and 30.4 at 6 and 12 months, respectively (mean improvements of 49.9 and 49.1 points, $p<0.0001$ each). Mean ODI improved from 55.2 at baseline to 32.5 and 31.4 at 6 and 12 months (improvements of 22.7 and 23.9 points, $p<0.0001$ each). SF-36 physical component summary improved from 31.7 at baseline to 40.2 and 40.3 at 6 and 12 months ($p<0.0001$). At 6 and 12 months, 93 and 87% of subjects, respectively, were satisfied and 92 and 91%, respectively, would have the procedure again.	Latest publication with longer term follow-up included in table 2.

Duhon BS, Cher DJ, Wine, KD et al (2013). Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. Medical Devices Evidence and Research (6) 219-29	Prospective case series (cohort study) patients with SI joint degeneration or disruption who had minimally invasive fusion using the iFuse Implant System. n=32 (efficacy cohort) 94 (safety cohort) Follow-up: 6 months (n=26)	3 implants were used in 80% of patients; 2 patients had staged bilateral implants. 23 adverse events occurred within 1 month of surgery and 29 additional events occurred between 30 days and latest follow-up. 6 adverse events were severe but none were device-related. In the effectiveness cohort, mean (+/- standard deviation) SI joint pain improved from a baseline score of 76 (+/-16.2) to a 6-month score of 29.3 (+/-23.3, an improvement of 49 points, P<0.0001), mean ODI improved from 55.3 (+/-10.7) to 38.9 (+/-18.5, an improvement of 15.8 points, P<0.0001) and SF-36 PCS improved from 30.7 (+/-4.3) to 37.0 (+/-10.7, an improvement of 6.7 points, P=0.003). 90% of subjects who were ambulatory at baseline regained full ambulation by month 6; median time to full ambulation was 30 days. Satisfaction was high at 85%.	Latest publication with longer term follow-up included in table 2.

Endres S and Ludwig E (2013). Outcome of distraction interference arthrodesis of the sacroiliac joint for sacroiliac arthritis. Indian Journal of Orthopaedics (47) 5 437-42 .	Retrospective case series n=19 patients with refractory severe pain of the SI joint. distraction arthrodesis of the SI joint –DIANA cage (posterior, longitudinally inserted into SI joint) Follow-up: 13.2 months mean	All patients had an instrumented lumbar or lumbosacral fusion. The overall fusion rate of SI joint was 78.9% (15/19 joints). All patients demonstrated significant improvement in VAS and ODI scores compared to preoperative values. The mean VAS score was 8.5 before surgery and was 6 at final followup, demonstrating 30% improvement. The mean ODI scores were 64.1 before surgery and 56.97 at the final follow-up, demonstrating 12% improvement.	Larger studies included in table 2.
Gaetani P, Miotti D, Risso A et al (2013). Percutaneous arthrodesis of sacro-iliac joint: a pilot study. Journal of Neurosurgical Sciences (57) 4 297-301.	Retrospective case series n=12patients with SI joint disruption had minimally invasive SI iFuse arthrodesis system. Follow-up:10 months mean (range 8-18 months).	Mean improvement in pain on NRS of 4 points, back related function on ODI by 19.4 points, and in quality of life measured using RDQ of 13.6 points (all P=0.01). Local hematoma requiring drainage was apparent in 2 patients. Patient satisfaction was 100%. All 3 month CT scans showed initial fusion.	Study included in systematic review (Heiney 2015) added to table 2.
Graham-Smith A, Capobianco R, Cher D et al (2013). Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. Annals of Surgical Innovation & Research [Electronic Resource] (7) 1 14	Retrospective comparative case series (cohort study) n=263 patients with SI joint pain treated by either an open surgical technique using a combination of screws and cages (n=149) or a minimally invasive surgical (MIS) technique with a series of titanium plasma spray (TPS) coated triangular implants (n=114). Follow-up: 24 months	MIS operative measures of EBL, operating time and length of hospitalization were significantly lower than open surgery ($p<0.001$). Pain relief, measured as change from baseline to 12 months in VAS pain rating, was 3.5 points lower in the MIS vs. OS group (-6.2 vs. -2.7 points, $p<0.001$). When matched for age, gender and a history of prior lumbar spinal fusion, postoperative pain scores were on average 3.0 points (95% CI 2.1 - 4.0) lower in MIS vs. OS (rANOVA $p<0.001$).	Study included in systematic review (Heiney 2015) added to table 2.

Hayes, and Inc (2011). Health Technology Assessment Database 2011 PT 3. Sacroiliac joint fusion for treatment of adult low back pain (Structured abstract)			Bibliographic record of a published HTA
Hayes , and Inc (2014) Health Technology Assessment Database 2014 PT 3 iFuse implant system (SI-BONE Inc.) for sacroiliac joint fusion for treatment of low back pain (Structured abstract)			Bibliographic record of a published HTA
Hayes , and Inc (2014). Health Technology Assessment Database 2014 PT 3 Open surgery for sacroiliac joint fusion for the treatment of low back pain (Structured abstract).			Bibliographic record of a published HTA
Kim JT, Rudol, LM and Glaser JA (2013). Outcome of percutaneous sacroiliac joint fixation with porous plasma-coated triangular titanium implants: an independent review. The open orthopaedics journal (7) 51-6	Retrospective case series n=31 patients had percutaneous fixation of the SI joint with porous coated triangular titanium implants	27 patients expressed satisfaction, 4 patients did not. Pain relief was noted to be Complete (16 patients), Excellent (5 patients), Good (9 patients), and Fair (1 patients). Four patients had postoperative complications. These were infected hematoma (2), L5 nerve root irritation (1), and L5-S1 discitis (1). One patient required revision. On 6 month postop CT scan, 18/19 patients had radiographic evidence of bone ingrowth and bone into or across the SI joint was evident in 8/19 patients. Lucency was noted around at least one implant in 5/19 patients.	Larger studies included in table 2.

Khurana A, Guha AR, Mohanty K and Ahuja S (2009). Percutaneous fusion of the sacroiliac joint with hollow modular anchorage screws: clinical and radiological outcome. Journal of Bone & Joint Surgery - British Volume (91) 5 627-31 May.	Retrospective case series n=15 patients with SI joint degeneration who had percutaneous sacroiliac fusion using hollow modular anchorage screws filled with demineralised bone matrix. Follow-up: 17 months mean (9-39 months)	No post-operative clinical or radiological complications. The mean SF-36 scores improved from 37 (23 to 51) to 80 (67 to 92) for physical function and from 53 (34 to 73) to 86 (70 to 98) for general health ($p = 0.037$). The mean Majeed's score improved from 37 (18 to 54) pre-operatively to 79 (63 to 96) post-operatively ($p = 0.014$). There were 13 good to excellent results. 2 had persistent pain probably due to concurrent lumbar pathology.	Study included in systematic review (Heiney 2015) added to table 2.
Lee DJ, Kim SB et al (2016). Stereotactic guidance for navigated percutaneous sacroiliac joint fusion. Journal of Biomedical Research (30) 2 162-167	image guidance for minimally invasive percutaneous SI fusion with threaded titanium cage(s) packed with autograft and/or allograft in 2 patients.	Image-guidance allowed for implant placement in the SI joint with a small skin incision. In one patient, the SI joint cage had to be revised secondary to the anterior breach of sacrum.	Describes technique.
Ledonio CG, Polly DW and Swiontkowski MF (2014). Minimally invasive versus open sacroiliac joint fusion: are they similarly safe and effective? Clinical Orthopaedics & Related Research (472) 6: 1831-38.	Comparative cohort study (retrospective) MIS cohort n=22 (iFuse implant system), lateral approach Follow-up: median 15 months. Open cohort n=22 (3 hole, 4.5mm plate, autograft packed within joint), anterior approach through an ilioingunial incision. Follow-up: median 13 months	Patients in the open group had a higher mean EBL (681 mL versus 41 mL, $p < 0.001$). Mean surgical time and LOS were shorter in the MIS group than in the open group (68 minutes versus 128 minutes and 3.3 days versus 2 days, $p < 0.001$ for both). With the numbers available, mean postoperative ODI scores were not different between groups (47% versus 54%, $p = 0.272$). Pulmonary embolism in 1 patient in each group. 2 revisions in each group, in MIS group due to halo formation on the sacral side with recurring SI joint pain; in open group due to failed implant in 1 and nerve root irritation in the other.	Study included in systematic review (Heiney 2015) added to table 2.

Ledonio, CG, Polly DW et al (2014). Comparative effectiveness of open versus minimally invasive sacroiliac joint fusion. Medical Devices Evidence and Research (7): 187-93.	Comparative cohort study (retrospective) Patients with SI joint disruption/degenerative sacroiliitis. MIS cohort n=17 (iFuse implant system), lateral approach Follow-up: 12 months. Open cohort n=22 (3 hole, 4.5mm plate, autograft packed within joint), anterior approach through an ilioingunial incision. Follow-up: 24 months	Surgical time and hospital stay were significantly shorter in the MIS group than in the open group. Preoperative ODI was significantly greater in the open group (median 64 [44-78]) than in the MIS group (median 53 [14-84]). Postoperative improvement in ODI was statistically significant within and between groups, with MIS resulting in greater improvement. Adverse events: MIS group: transient trochanteric bursitis (3), haematoma (1), toe numbness (1), revision due to malpositioned implant (1). Revision in 2 patients in open group due to failed implant in 1 and nerve root irritation in the other.	Study included in systematic review (Heiney 2015) added to table 2.
Lingutla KK, Pollock R, and Ahuja S (2016). Sacroiliac joint fusion for low back pain: a systematic review and meta-analysis. European Spine Journal vol 25 (6), pp 1924-31.	Systematic review and meta-analysis of observational studies n=6 studies on patients with SIJF for low back pain. Intervention: any type of SIJF, both standard open and minimally invasive procedures. Mean follow-up: 17.6 months.	All outcomes showed statistical and clinical improvement (VAS pain MD: 54.8; 95 % CI 48.6, 61.0; n = 380; p < 0.001, ODI MD: 14.5; 95 % CI 8.4, 20.6; n = 102; p < 0.001, SF-36 PCS MD: -19.5; 95 % CI -24.7, -14.2; n = 140; p < 0.001, SF-36 MCS MD: -8.5; 95 % CI -12.9, -4.1; n = 198; p < 0.001 and Majeed score MD: -35.4; 95 % CI -48.5, -22.2; n = 140; p < 0.001). SIJF appears to be a satisfactory procedure for alleviating pelvic girdle pain.	Studies on both standard and minimally invasive fusion surgeries were included. Outcomes not reported separately for both type of interventions. Studies included in systematic review (Heiney 2015) added to table 2.
Manfre, L (2014). Percutaneous Sacroiliac Joint Fixation in Sacroiliac Instability. The First Case Report Using a Fully CT-Guided Technique. Interventional Neuroradiology (20) 5 621-5.	Case report describes a patient with painful SIJ instability treated with a fully CT guided technique in simple analogue sedation.	CT-guided SIJ fusion using titanium implants seems to be an easy-to-perform safe procedure when SIJ instability has to be treated.	Larger studies included in table 2.

Mason LW, Chopra I and Mohanty K (2013). The percutaneous stabilisation of the sacroiliac joint with hollow modular anchorage screws: a prospective outcome study. European Spine Journal (22) 10 2325-31.	Case series (retrospective) n=55 patients with sacroiliac joint pain MIS-lateral approach using HMA screw packed with DBM Follow-up: 36 months	The mean preoperative SF-36 scores were 26.59 for physical health and 40.38 for mental health. The mean postoperative SF-36 scores were 42.93 for physical health and 52.77 for mental health. The mean visual analogue pain scores were 8.1 preoperative and 4.5 postoperative. The mean pelvic specific scoring were 36.9 preoperative and 64.78 postoperative. We noted that patients who had previous instrumented spinal surgery did significantly worse than those who had not. We had two nerve root-related complications.	Study included in systematic review (Heiney 2015) added to table 2.
Miller LE and Block JE (2014). Minimally invasive arthrodesis for chronic sacroiliac joint dysfunction using the SImmetry SI Joint Fusion system. Medical Devices Evidence and Research (7) 125-30		This report is to describe the minimally invasive SI Joint Fusion System, including patient selection criteria, implant characteristics, surgical technique, postoperative recovery, and biomechanical testing results.	General review
Papanastassiou ID, Setzer M et al (2011). Minimally invasive sacroiliac fixation in oncologic patients with sacral insufficiency fractures using a fluoroscopy-based navigation system. Journal of Spinal Disorders & Techniques (24) 2 76-82.	Retrospective case series n=6 sacral insufficiency fractures in oncology patients. Multiple long screws that cross both SI joints and engage bilateral iliac bones were fixed percutaneously. Follow-up: mean 19 months.	In 1 case, a revision of a screw was required due to radiculopathy. There was no perioperative morbidity or mortality. No hardware failure was encountered. There was significant improvement in KPS (P=0.04) and pain levels (P=0.02).	Study included in systematic review (Zaidi 2015) added to table 2.

Polly DW., Cher DJ, Wine KD et al (2016). Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. Neurosurgery (77) 5 674-90; discussion 690-1.	Randomised controlled trial n=148 patients with SIJ dysfunction. MI SIJ fusion (n=102) versus non-surgical management (n=46) Follow-up: 12 months	Six-month success rates were higher in the surgical group (81.4% vs 26.1%; posterior probability of superiority <0.9999). Clinically important ($ 15 point) Oswestry Disability Index improvement at 6 months occurred in 73.3% of the SIJ fusion group vs 13.6% of the nonsurgical management group (P< .001). At 12 months, improvements in SIJ pain and Oswestry Disability Index were sustained in the surgical group. Subjects who crossed over had improvements in pain, disability, and quality of life similar to those in the original surgical group. Adverse events were slightly more common in the surgical group (1.3 vs 1.1 events per subject; P = .31).	Study with longer follow-up included in table 2.

Rudolf L and Capobianco R (2014). Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants. The open orthopaedics journal (8) 375-83	Case series n=17 patients treated with MIS SI joint fusion (iFuse implant system) for degenerative sacroiliitis and/or sacroiliac joint disruptions. Lateral approach. Follow-up: 60 months	Pain on VAS improved from 8.3 at baseline to 2.4 at 5 years; 88% of patients reached Substantial Clinical Benefit. Mean ODI score at 5 years was 21.5 (SD 22.7). Patient satisfaction achieved at 12 months was maintained for 5 years (82%). A qualitative review of x-ray and CT imaging showed increased bone density immediately adjacent to all implants, intra-articular osseous bridging in 87% of patients and no evidence of implant loosening or migration. Long-term clinical and radiographic outcomes after MIS SIJ fusion are favourable. Clinical improvements observed at 12 months postoperatively were maintained at 5 years.	Study included in systematic review (Heiney 2015) added to table 2.
Rudolf L(2013). MIS Fusion of the SI Joint: Does Prior Lumbar Spinal Fusion Affect Patient Outcomes? The open orthopaedics journal (7) 163-8	Case series (sub group analysis) n=40 patients with SI joint pain. MIS- lateral approach using iFuse implant system (18 no prior fusion, 15 prior fusion, 7 prior concomitant lumbar pathology treated non-surgically). Follow-up: 12 and 24 months	All subgroups experienced a clinically and statistically significant reduction in pain at all time points (mean change >2 points, $p<0.001$). There was a statistically significant effect of cohort ($p=0.045$), with the NF cohort (no prior lumbar spinal fusion) having a somewhat greater decrease in pain (by approximately 1 point) compared to the other 2 groups (PF and LP).Patient reported satisfaction by cohort was: 89% (NF), 92% (PF) and 63% (LP).Overall satisfaction rate was 87%.	Study included in systematic review (Heiney 2015) added to table 2.

Rudolf L (2012). Sacroiliac Joint Arthrodesis-MIS Technique with Titanium Implants: Report of the First 50 Patients and Outcomes. The open orthopaedics journal (6) 495-502 .	Case series (retrospective) n=50 treated by minimally invasive sacroiliac joint fusion using a series of triangular, porous plasma spray coated titanium implants (iFuse implant system) Lateral approach Follow-up: 40 months	An early and sustained statistically significant improvement in pain function was identified at all post-operative time points (ANOVA, p<0.000). A clinically significant improvement (>2 point change from baseline) was observed in 7 out of 9 domains of daily living. The complication rate was low and more than 80% of patients would have the same surgery again.	Study included in systematic review (Heiney 2015) added to table 2.
Sachs D, Capobianco R, Cher D et al (2014). One-year outcomes after minimally invasive sacroiliac joint fusion with a series of triangular implants: a multicenter, patient-level analysis. Medical Devices Evidence and Research (7) 299-304	Retrospective analysis n=144 patients with SI joint pain refractory to conservative care. SI joint fusion using a series of triangular, titanium plasma spray-coated implants (iFuse implant system) lateral approach Follow-up: mean 16 months	At follow-up, mean (95% CI) visual analogue scale pain scores improved by 6.1 points (5.7-6.6). Substantial clinical benefit, defined as a decrease in pain by >2.5 points or a score of 3.5 or less, was achieved in 91.9% of patients (95% CI 83.9%-96.1%), and 96% (95% CI 86.3%-98.8%) of patients indicated they would have the same surgery again.	Study included in systematic review (Heiney 2015) added to table 2.
Sachs D and Capobianco R (2013). Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. Advances in Orthopaedics 536128	Case series (retrospective) n=40 patients SI joint pain refractory to conservative care MIS SI joint fusion with the iFuse Implant System Follow-up: 12 months	Postoperative complications were minimal and included transient trochanteric bursitis (5%), facet joint pain (20%), and new low back pain (2.5%). There were no reoperations at one year. Mean pain score improved from 8.7 (1.5 SD) at baseline to 0.9 (1.6) at 12 months, a 7.8-point improvement (P < .001). Patient satisfaction was very high.	Study included in systematic review (Heiney 2015) added to table 2.

Sachs D and Capobianco R (2012). One year successful outcomes for novel sacroiliac joint arthrodesis system. Annals of Surgical Innovation & Research [Electronic Resource] 6 (1): 13	Case series (retrospective) n=11 patients SI joint pain refractory to conservative care MIS SI joint fusion system iliosacral approach Follow-up: 12 months	Mean baseline pain score (SD) was 7.9 (+/- 2.2). Mean pain score at the 12 month follow up interval was 2.3 (+/- 3.1), resulting in an average improvement of 6.2 points from baseline, representing a clinically and statistically significant (p=0.000) improvement. Patient satisfaction was very high with 100% indicating that they would have the same surgery again for the same result. Piriformis syndrome in 1 patient and low back pain in 1 reported.	Study included in systematic review (Heiney 2015) added to table 2.
Saavoss JD, Koenig L and Cher DJ (2016). Productivity benefits of minimally invasive surgery in patients with chronic sacroiliac joint dysfunction. Clinicoeconomics & Outcomes Research (8) 77-85	Regression modelling using data from the National Health Interview Survey was applied to determine the relationship between responses to selected interview questions related to function and economic outcomes. Regression coefficients were then applied to prospectively collected, individual patient data in a randomized trial of SIJ fusion (INSITE, NCT01681004) to estimate expected differences in economic outcomes across treatments.	Patients who receive SIJ fusion using iFuse Implant System() have an expected increase in the probability of working of 16% (95% confidence interval [CI] 11%-21%) relative to nonsurgical patients. The expected change in earnings across groups was US $3,128 (not statistically significant). Combining the two metrics, the annual increase in worker productivity given surgical vs nonsurgical care was $6,924 (95% CI $1,890-$11,945).	Study estimates SIJ fusion on worker productivity (economic outcomes). Out of scope.

Schroeder JE, Cunningham ME et al (2013). Early results of sacro-iliac joint fixation following long fusion to the sacrum in adult spine deformity. Hosp Spec Surg Journal (10) 1, 30-5	Retrospective case series n=6 patients having percutaneous SIJ fixation (with triangular TPS coated implants) for SIJ pain following corrective scoliosis surgery. Follow-up: 10.2 months mean (range 4-15 months).	There were no complications. Discharged on post-operative day 2. Leg VAS score improved from 6.5 to 2.0 (P<0.005; minimal clinically important difference (MCID) 1.6). Back VAS score decreased from 7.83 to 2.67 mm (P<0.005; MCID 1.2). ODI scores dropped from 22.2 to 10.5 (P=0.0005; MCID 12.4). SRS22 scores increased from 2.93 to 3.65 (P=0.035; MCID 0.2) with the largest increases in the pain, function, and satisfaction domains of the questionnaires.	Study included in systematic review (Heiney 2015) added to table 2.
Vanaclocha VV, Verdu-Lopez F, Sanchez-Pardo M et al (2014). Minimally invasive sacroiliac joint arthrodesis: experience in a prospective series with 24 patients. J Spine. 3(5):185 doi:10.4172/2165-7939.1000185	Case series n=24 iFuse Implant system-lateral approach Follow-up: 23 months	VAS: 8.7 pre-op, 1.7 at1 year, 2.1at 4.5 years. ODI: 54.1 pre-op, 14.3 at 1 year, 16.3 at 4.5 years. Surgical time 48 minutes. Blood loss 58 ml. Immediate post-operative pain in 4 patients resolved. Temporary post-operative radicular pain in 2 reported.	Study included in systematic review (Heiney 2015) added to table 2.

Whang P, Cher D, Polly D et al (2015). Sacroiliac Joint Fusion Using Triangular Titanium Implants vs. Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial. International Journal of Spine Surgery (9) 6	Randomised controlled trial n=148 with SI joint dysfunction due to degenerative sacroiliitis or sacroiliac joint disruptions Minimally invasive SI joint fusion with triangular titanium implants (N=102) versus non-surgical management (NSM, n=46). Follow-up: 6 months	By 6 months, success rates were 81.4% in the surgical group vs. 23.9% in the NSM group (difference of 56.6%, 95% posterior credible interval 41.4-70.0%, posterior probability of superiority >0.999). Clinically important (>15 point) ODI improvement at 6 months occurred in 75% of surgery subjects vs. 27.3% of NSM subjects. At six months, quality of life improved more in the surgery group and satisfaction rates were high. The mean number of adverse events in the first six months was slightly higher in the surgical group compared to the non-surgical group (1.3 vs. 1.0 events per subject, p=0.1857).	Latest publication with longer term follow-up included in table 2.
Wise CL and Dall BE (2008). Minimally invasive sacroiliac arthrodesis: outcomes of a new technique. Journal of Spinal Disorders & Techniques (21) 8 579-84.	Prospective cohort study n=13 patients with SIJ degeneration. Minimally invasive sacroiliac arthrodesis using percutaneously inserted fusion cages filled with bone morphogenic protein. Follow-up: mean 29 months.	The overall fusion rate was 89% (17/19 joints). Significant improvements were seen in final low back pain score on a visual analogue scale (0 to 10) (average improvement 4.9, P< or =0.001). Leg pain improved an average of 2.4 (P=0.013). Dyspareunia improved an average of 2.6 (P=0.0028). One patient was revised to an open arthrodesis secondary to non-union and persistent pain. There were no infections or neurovascular complications.	Study included in systematic review (Zaidi 2015) added to table 2.

Woods M, Birkhol, D et al (2014). Utility of Intraoperative Neuromonitoring during Minimally Invasive Fusion of the Sacroiliac Joint. Advances in Orthopaedics 154041	Retrospective case series n=37 Minimally invasive surgical sacroiliac joint fusion using a series of triangular, titanium porous plasma coated implants.	Sensitivity of EMG was 80% and specificity was 97%. Intraoperative neuromonitoring potentially avoided neurologic sequelae as a result of improper positioning in 7% of implants.	study reports intraoperative neuromonitoring.

Appendix B: Related NICE guidance for minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain

Guidance	Recommendations

Interventional procedures	**Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica. NICE interventional procedure guidance 544 (2016).** 1.1 Current evidence on percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is inconsistent and of poor quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to do percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica should: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In particular, patients should be informed about other treatment options, about the possibility that the procedure may not relieve their symptoms, and about the risk of a flare-up of their pain following treatment. In addition, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency treatment of the intervertebral disc annulus (see section 7.2). 1.3 NICE encourages further research into percutaneous electrothermal treatment of the intervertebral disc annulus. Further research should document details of patient selection, including the duration of their symptoms. It should report precise details of the technique used for treatment. Outcome measures should include pain relief and quality of life. Long-term follow-up data should include details of any subsequent procedures. This replaces previous guidance on percutaneous intradiscal electrothermal therapy for low back pain (NICE interventional procedure guidance 319). **Percutaneous coblation of the intervertebral disc for lower back pain and sciatica. NICE interventional procedure guidance 543 (2016).** 1.1 Current evidence on percutaneous coblation of the intervertebral disc for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is adequate and includes large numbers of patients with appropriate follow-up periods. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 As part of the consent process, patients should be informed that there is a range of treatment options available to them and also that further procedures may be needed.

This replaces previous guidance on percutaneous disc decompression using coblation for lower back pain (NICE interventional procedure guidance 173).

Transaxial interbody lumbosacral fusion. NICE interventional procedure guidance 387 (2011).

1.1 Current evidence on the efficacy of transaxial interbody lumbosacral fusion is limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake transaxial interbody lumbosacral fusion should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and its risks, specifically including the small risk of rectal perforation in patients with higher bowel disease, or a history of pelvic disease or previous pelvic surgery. They should provide patients with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having transaxial interbody lumbosacral fusion (see section 3.1).

1.3 This procedure should only be carried out by surgeons with expertise in the surgical management of spinal disease and specific training in the technique. They should perform their initial procedures with an experienced mentor.

1.4 NICE encourages further research into transaxial interbody lumbosacral fusion. Research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and late complications. NICE may review this procedure on publication of further evidence.

Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedure guidance 366 (2010).

This document replaces previous guidance on non-rigid stabilisation procedures for the treatment of low back pain (interventional procedure guidance 183).

1.1 Current evidence on the efficacy of non-rigid stabilisation techniques for the treatment of low back pain shows that these procedures are efficacious for a proportion of patients with intractable back pain. There are no major safety concerns. Therefore these procedures may be used provided that normal arrangements are in place for clinical governance, consent and audit.

	1.2 Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options. **Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010).** This guidance replaces previous guidance on laser lumbar discectomy (interventional procedure guidance 27). 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal laser ablation in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patients selected for the procedure should be limited to those with severe pain refractory to conservative treatment, in whom imaging studies show bulging of an intact disc, and who do not have neurological deficit requiring surgical decompression. **Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedure guidance 321 (2009).** 1.1 Current evidence on the safety and efficacy of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake lateral interbody fusion in the lumbar spine should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having lateral interbody fusion in the lumbar spine (see section 3.1). 1.3 This procedure should only be carried out by surgeons with specific training in the technique, who should perform their initial procedures with an experienced mentor. 1.4 NICE encourages further research into lateral interbody fusion in the lumbar spine. Research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and late complications. NICE may review the procedure on publication of further evidence. **Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009).**

	This document replaces previous guidance on prosthetic intervertebral disc replacement (interventional procedure guidance 100). 1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 A multidisciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated. 1.3 The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery. **Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009).** 1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. 1.2 Clinicians wishing to undertake percutaneous endoscopic laser lumbar discectomy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having percutaneous endoscopic laser lumbar discectomy (see section 3.1). 1.3 Surgeons undertaking this procedure should have specific training in the use of lasers and in endoscopy of the spinal canal. 1.4 NICE encourages further research into percutaneous endoscopic laser lumbar discectomy and may review the procedure on publication of further evidence. Research studies should provide long-term outcome data. **Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005).**

	1.1 Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having automated mechanical percutaneous lumbar discectomy. The Institute may review the procedure upon publication of further evidence. **Endoscopic laser foraminoplasty. NICE interventional procedure guidance 31 (2003).** 1.1 Current evidence of the safety and efficacy of endoscopic laser foraminoplasty does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake endoscopic laser foraminoplasty should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's information for the public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Further research into safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.
NICE guidelines	**Low back pain in adults: early management. NICE clinical guideline 88 (2009). 'This guidance is currently under review and is expected to be updated in 2016'.**

Appendix C: Literature search for minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	01/08/2016	Issue 7 of 12, July 2016
HTA database (Cochrane)	01/08/2016	Issue 3 of 4, July 2016
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	01/08/2016	Issue 7 of 12, July 2016
MEDLINE (Ovid)	01/08/2016	1946 to July Week 3 2016
MEDLINE In-Process (Ovid)	01/08/2016	July 29, 2016
EMBASE (Ovid)	01/08/2016	1974 to 2016 Week 31
PubMed	01/08/2016	n/a
BLIC (British Library)	01/08/2016	n/a

Trial sources searched on 21/06/2016

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched on 21/06/2016

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 Minimally Invasive Surgical Procedures/

2 Spinal Fusion/

3 ((sacrum or SI or sacroiliac or sacro-iliac or SIJ) adj4 (fusion or fuse* or arthrodes* or surg* or immobili* or fixat*)).tw.

4 (MIS adj4 fus*).tw.

5 (minimal* adj4 invas* adj4 fus*).tw.

6 (spin* adj4 (hardware or fus* or fixat*)).tw.

7 Titanium/ and "Prostheses and Implants"/

8 (titanium adj4 implant*).tw.

9 BNP.tw.

10 'bone morphogenetic protein*'.tw.

11 (ifuse or i-fuse).tw.

12 SImmetry.tw.

13 SI-BONE.tw.

14 or/1-13

15 Sacroiliac Joint/

16 ((sacrum or SI or sacroiliac or sacro-iliac or SIJ) adj4 (dysfunct* or disrupt* or pain* or degenerat* or inflamm* or injur* or hypermobil* or syndrome* or fracture*)).tw.

17 sacroiliitis.tw.

18 Pelvic Bone/

19 (pelvic adj4 (bone* or ring*)).tw.

20 or/15-19

21 14 and 20

22 animals/ not humans/

23 21 not 22